

R.J. Reynolds Tobacco Company's Application for Six Camel SNUS Smokeless Tobacco Minimizes its Appeal to Adolescents and the Likelihood that Youth and Adolescents Will Initiate Smokeless Tobacco or Smokeless Tobacco with Other Products

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RJ Reynolds Tobacco Company's (RJR) Modified Risk Tobacco Product (MRTP) application for Six Camel Snus smokeless tobacco products does not adequately consider the appeal or impact the product and its related claims can have on youth or adolescents, including whether and to what extent their products will result in youth misperceptions about the product risks, and whether their snus will result in initiation among non-users, and dual or poly-use. Further, their MRTP application fails to consider the role that their flavored products will have on youth. Therefore, the FDA should deny RJR's MRTP application for their six camel snus products.

On December 18, 2017, FDA filed for substantive scientific review of six RJ Reynolds Tobacco Company's (RJRT) Modified Risk Tobacco Product (MRTP) Applications for the following six varieties of its Camel Snus smokeless tobacco products: Camel Snus Frost, Camel Snus Frost Large, Camel Snus Mellow, Camel Snus Mint, Camel Snus Robust Camel Snus Winterchill. RJR requests that the U.S. Food and Drug Administration issue orders authorizing RJR to advertise each of its Camel Snus styles (Frost, Frost Large, Winterchill, Robust, Mellow, and Mint, collectively, "Camel Snus") as a modified risk tobacco product ("MRTP") pursuant to Section 911 of The Family Smoking Prevention and Tobacco Control Act ("the TCA"). RJR proposes three different modified risk advertising executions for each of the six Camel Snus styles and is requesting a total of eighteen (18) MRTP orders.

Section 911 of the Family Smoking Prevention and Tobacco Control Act¹ and FDA's Guidance for Industry on Modified Risk Tobacco Product (MRTP) Applications² spell out the rigorous requirements that MRTP applicants must meet before a product can be deemed a "modified risk tobacco product" and can be marketed with MRTP claims. In particular, to market Snus with the MRTP claims stated above, RJR must prove using substantial and objective scientific evidence that the new product, *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.

In fulfilling the MRTP application requirements specified in section 911(g), FDA recommends in its MRTP Guidance that applicants submit, among other things, the following data and information:

¹ Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. §387k, Pub. L. 111-31, 123 Stat. 1776 (2009).

² Food and Drug Administration, Modified Risk Tobacco Product Applications, Draft Guidance (March 2012). Available at <https://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM297751.pdf>

- 1) Scientific evidence regarding the effect that tobacco products and its marketing will have on increasing the likelihood that *non-users* (including never users and former users) will start using the product (Guidance, p. 20);
- 2) Data and information on how consumers *actually use* the product, including data and information addressing concurrent use of multiple products containing nicotine or tobacco (Guidance, p. 15), and scientific evidence demonstrating that consumers actually use the product in a way that exposes them to the claimed reduced level of substances or harm (Guidance, p. 17);
- 3) Human studies that evaluate consumer understanding and perceptions of the product, including its labeling, marketing, and advertising, including:
 - a. The ability of consumers to understand the modified risk claims and the significance of the information in the context of one’s health;
 - b. Consumers’ beliefs about the health risks of using the product relative to other tobacco products;
 - c. Consumer beliefs about the health risks of using the product relative to cessation aids; and
 - d. Consumer beliefs about the risks of using the product relative to quitting all tobacco use (Guidance, pp. 20-21)

RJR has not met these criteria because the data necessary to support this claim are lacking or are presented in a way that is misleading. In addition, the proposed Camel Snus marketing is likely to appeal to tobacco non-users, including youth, something that RJR also ignores.

For these reasons, and others explained more fully below, FDA should deny RJR’s MRTP application.

The proposed Camel Snus marketing is likely to appeal to tobacco non-users, including youth.

Because RJR’s application did not consider the impact of Snus on adolescent use, it did not demonstrate that the product, as actually used by consumers, will benefit the health of the population as a whole, including current non-users; in particular, it did not provide any scientific evidence regarding the effect that Snus and its marketing would have on increasing the likelihood that adolescents who are currently not tobacco users will start using Snus.

Despite section 911(g)’s requirement, RJR failed to provide adequate scientific evidence demonstrating that their Snus products would “benefit the health of the population as a whole,” in particular non-users (including adolescents) as well as current users of other tobacco products.

In their application RJR argued that there is no evidence for a gateway effect; that is, that there is no evidence that those who use smokeless tobacco will subsequently use cigarettes or other tobacco products. However, the application’s executive summary (pages 205-206 and 208) not only includes multiple prospective studies that demonstrate this association,³ the application also fails to include a number of additional studies demonstrating that youth who use smokeless tobacco are more likely to smoke cigarettes in the future.⁴

³ Severson, H. H., Forrester, K. K., & Biglan, A. (2007). Use of smokeless tobacco is a risk factor for cigarette smoking. *Nicotine Tob Res*, 9(12), 1331-1337.

Tomar SL. Is use of smokeless tobacco a risk factor for cigarette smoking? The U.S. experience. *Nicotine Tob Res*. 2003 Aug;5(4):561-9.

Joffer J, Burell G, Bergström E, Stenlund H, Sjörs L, Jerdén L. Predictors of smoking among Swedish adolescents. *BMC Public Health*. 2014 Dec 17;14:1296.

Taylor N, Choi K, Forster J. Snus use and smoking behaviors: preliminary findings from a prospective cohort study among US Midwest young adults. *Am J Public Health*. 2015 Apr;105(4):683-5.

⁴ Walsh MM, Langer TJ, Kavanagh N, Mansell C, MacDougal W, Kavanagh C, Gansky. Smokeless tobacco cessation cluster randomized trial with rural high school males: intervention interaction with baseline smoking. *Nicotine Tob Res*. 2010 Jun;12(6):543-50.

Furthermore, RJR cites a number of studies that they conclude demonstrate a "reverse gateway" effect of smokeless tobacco, because youth who initiate tobacco use with cigarettes have been shown to be more likely to smoke cigarettes at follow-up than youth who initiate with smokeless tobacco.⁵ This conclusion ignores the self-evident fact that youth who initiate tobacco use with cigarettes *are already smoking cigarettes*, and therefore are not an appropriate comparison group for calculating the onset of smoking among youth. Clearly, youth who have already smoked are the risk-group most likely to continue smoking. RJR uses this apples-to-oranges comparison with the "positive gateway" studies to dismiss completely the consistent, positive, prospective association between smokeless tobacco use among youth who have never smoked and subsequent onset of cigarette smoking.

RJR's application did not include information from studies with adolescents younger than 18

RJR did not provide any reliable information in its application on whether adolescents would be interested in using Snus, if adolescents would initiate nicotine/tobacco use with Snus, if adolescents would switch from another tobacco product to Snus, or if adolescents would use Snus along with other tobacco products.

One way to obtain information on adolescents' interests and behavior is to conduct studies with adolescents. However, neither RJR nor any other tobacco company should be permitted to conduct research on youth below the legal age for tobacco use (21, to be conservative) because they could use such information to design marketing campaigns to attract youth to their products. A different way to get at adolescents' interest and behavior is relying on research on other, similar products conducted with no direct or indirect involvement of tobacco companies or their agents.⁶

The available evidence reported in scientific studies on currently marketed novel tobacco products conducted independent of the tobacco industry indicates that the introduction of novel products will attract adolescent non-users into initiating use. Adolescents' decisions to adopt use of any tobacco product are based on several considerations, including whether the product appeals to them, the product's flavors, smell and taste, the product's perceived harm reduction, and the ease and location of use.⁷ The marketing of Snus with harm reduction claims and the claim that they are "smokeless" makes it likely that these products will appeal to youth.

Concern that individuals "misperceive" the relative harms of cigarettes and smokeless tobacco is overstated.

On page 84, the executive summary states, "In developing modified risk advertising, RJR was acutely aware of the prevailing public misperception that use of smokeless tobacco, including snus, is at least as harmful as cigarette smoking. Studies that have evaluated consumer perceptions show that, contrary to the consensus in the public health and tobacco control communities, the public (including consumers) believes – erroneously – that smokeless tobacco products are as harmful as, or more harmful than, cigarettes."

Watkins SL, Glantz SA, Chaffee BW. Association of Noncigarette Tobacco Product Use with Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013-2015. *JAMA Pediatr.* 2018 Feb 1;172(2):181-187; Ary DV, Lichtenstein E, Severson HH. Smokeless tobacco use among male adolescents: patterns, correlates, predictors, and the use of other drugs. *Prev Med.* 1987 May;16(3):385-401.

⁵ Rodu B, Cole P. Evidence against a gateway from smokeless tobacco use to smoking. *Nicotine Tob Res.* 2010 May;12(5):530-4.

⁶ Institute of Medicine. 2012. *Scientific Standards for Studies on Modified Risk Tobacco Products.* Washington, DC: The National Academies Press. <https://doi.org/10.17226/13294>.

⁷ McKelvey, K., Ramos, M., Roditis, M., Ramamurthi, D., Halpern-Felsher, B. A Qualitative Analysis of Adolescents' Appeal of Various Tobacco Products. In preparation.

The idea that individuals, and in particular youth, misperceive the relative harms, believing that smokeless tobacco is as harmful as cigarette smoking, is flawed. There are multiple studies showing that youth perceive smokeless to be less harmful than cigarettes and other tobacco products.^{8,9} One study showed that adolescents rated various tobacco products as conferring significantly different levels of risks and benefits. Generally, adolescents rated cigarettes as most risky, followed by cigars and chew, with hookah and e-cigarettes rated as least risky.¹⁰

Other concerns about how adolescents might perceive these SNUS products include:

- Marketing Camel Snus as a product with "less risk" is problematic. There is a well-known tendency for the public to underestimate absolute risk when presented in reference to a higher risk alternative.¹¹
- The proposed Camel Snus advertisements, which tout smokeless tobacco as an acceptable alternative to smoking, would conflict and compete with messages not to initiate smokeless tobacco use, such as the FDA Real Cost campaign for rural youth. These competing messages are likely to engender confusion and limit the effectiveness of existing tobacco control efforts.¹²
- The message that Camel Snus contains "less risk" may generate perceptions that extend other alternative tobacco products, including conventional moist snuff and chewing tobacco, leading to increased appeal and uptake of other tobacco products, which would harm public health.

RJR and other Tobacco Companies should NOT be permitted to provide “educational” campaigns

RJR argues that education is needed about the relative risks smokeless tobacco and snus versus smoking and imply that they have developed such educational materials (Executive Summary pages 84-85) and again on page 195: The application notes, “education about relative risks of smokeless tobacco and snus versus smoking has the potential to mitigate the observed misperceptions about relative risk.” The MRTP application also suggests that "education" has the potential to "improve U.S. smokers' understanding of combustible nicotine sources compared to smoking."

This idea is problematic because no tobacco industry should be involved in any educational effort, and especially not for youth. Studies of past efforts from tobacco companies to provide tobacco education have found that industry-sponsored curricula are at best ineffective at reducing youth use.¹³ Instead, these industry-sponsored curricula provide the public with the sense that the industry is trying to prevent youth use of the product, thus creating a positive image of the industry while also subtly promoting smoking and maintaining a connection with a youth audience.^{14,15} Industry-sponsored curricula also downplay the highly addictive nature

⁸ Chaffee BW, Cheng J. Cigarette and Smokeless Tobacco Perception Differences of Rural Male Youth. *Tobacco Regulatory Science*, Volume 4, Number 4, July 2018, pp. 73-90(18)

⁹ Wray RJ, Jupka K, Berman S, Zellin S, Vijaykumar S. Young adults' perceptions about established and emerging tobacco products: results from eight focus groups. *Nicotine Tob Res.* 2012 Feb;14(2):184-90.

¹⁰ Roditis, M., Delucchi, K., Cash, D., & Halpern-Felsher, B. Adolescents' Perceptions of Health Risks, Social Risks, and Benefits Differ Across Tobacco Products. *Journal of Adolescent Health* 58 (2016) 558e566

¹¹ Rothman AJ, Kiviniemi MT. Treating people with information: an analysis and review of approaches to communicating health risk information. *J Natl Cancer Inst Monogr.* 1999(25):44-51.

¹² Tomar SL, Fox BJ, Severson HH. Is smokeless tobacco use an appropriate public health strategy for reducing societal harm from cigarette smoking? *Int J Environ Res Public Health.* 2009;6(1):10-24.

¹³ WHO. Tobacco industry interference with tobacco control. <http://www.who.int/tobacco/resources/publications/Tobacco Industry Interference-FINAL.pdf>. Accessed August 7, 2018.

¹⁴ WHO. Tobacco industry interference with tobacco control. <http://www.who.int/tobacco/resources/publications/Tobacco Industry Interference-FINAL.pdf>. Accessed August 7, 2018.

of nicotine and completely disregard how product marketing influences use,¹⁶ and tobacco industries have been shown to promote prevention programs that have been shown to be ineffective at reducing youth tobacco use.¹⁷ Further, exposure to tobacco-sponsored smoking prevention advertising on television is associated with youth having lower perceived risks of smoking and greater likelihood of smoking.¹⁸

The more relevant question to be answered is how will youth perceive Snus given the marketing claims, including how they perceive Snus compared to other tobacco products, and whether the marketing and appeal of this new tobacco product will result in lower perceptions of risk compared to other tobacco products, which then can result in use.

More specifically, the question is: Will Snus, with lower perceived risks, encourage never-smokers -- including adolescents -- who would otherwise not use any tobacco products to be more likely to try Snus?

In making its determination on whether to issue an MRTP order, FDA is required to take into account “the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application.”¹⁹

Thus, exposure to the marketing of Snus focusing on claims of reduced risks is likely to cause youth and adolescent never-smokers to initiate nicotine use with Snus. RJR’s application is silent on these important issues.

RJR’s application failed to consider the likelihood that the Snus flavors would appeal to youth and adolescents and encourage initiation among non-users.

RJR’s MRTP application includes the following six varieties of its Camel Snus smokeless tobacco products: Camel Snus Frost, Camel Snus Frost Large, Camel Snus Mellow, Camel Snus Mint, and Camel Snus Robust Camel Snus Winterchill.

RJR failed to provide any information on whether these flavored products will attract youth.

In order to attract young and new users, the tobacco industry adds characterizing flavors like mint, menthol, fruit, and candy to tobacco.²⁰ These flavors appeal to new users by masking the harsh taste of tobacco. Additionally, tobacco products with a characterizing flavor including fruit-flavored e-cigarettes²¹ and menthol cigarettes¹⁴ are perceived to be less harmful than unflavored or tobacco-flavored products. In addition, there is some evidence that menthol cigarettes are harder to quit.²² Snus is no exception in how tobacco flavors and

¹⁵ CDC Office on Smoking and Health. Tobacco industry-sponsored youth prevention programs in schools. April 2018. <https://www.voorheesville.org/site/handlers/filedownload.ashx?moduleinstanceid=538&dataid=1802&FileName=Tobacco%20industry%20sponsored%20youth%20prevention%20programsCDC.pdf>. Accessed on August 13, 2018.

¹⁶ Landman A, Ling PM, Glantz SA. Tobacco Industry Youth Smoking Prevention Programs: Protecting the Industry and Hurting Tobacco Control. American Journal of Public Health. 2002;92(6):917-930. doi:10.2105/ajph.92.6.917.

¹⁷ Mandel, LL., Bialous, SA, Glantz, SA. Avoiding “truth:” tobacco industry promotion of life skills training. J Adolescent Health. 2006 Dec;39(6):868-79

¹⁸ Wakefield, M., Terry-McElrath, Y., Emery, S., Saffer, H., Chaloupka, FJ, Szczyepka, G., Flay, B., O’Malley, PM, & Johnston, LD. Effect of televised, tobacco company-funded smoking prevention advertising on youth smoking-related beliefs, intentions, and behavior. Am J Public Health, 2006, Dec 96(12): 2154-60.

¹⁹ Section 911(g)(4)(C) of the Family Smoking Prevention and Tobacco Control Act.

²⁰ Brown JE, Luo W, Isabelle LM, Pankow JF. Candy flavorings in tobacco. N Engl J Med. 2014;370(23):2250-2252.

²¹ Pepper JK, Ribisl KM, Brewer NT. Adolescents’ interest in trying flavoured e-cigarettes. Tob Control. 2016;25(Suppl 2):ii62-ii66. doi:10.1136/tobaccocontrol-2016-053174.

²² Pletcher MJ, Hulley BJ, Houston T, Kiefe CI, Benowitz N, Sidney S. Menthol cigarettes, smoking cessation, atherosclerosis, and pulmonary function. 2006;166.

packaging elements affect youths' harm perceptions: Youth shown packages for smokeless tobacco with or without a flavor descriptor (primarily for snus and dissolvable tobacco) were more likely than older adults to associate the flavor descriptor with better taste, more appeal, and lower health risks.²³

Flavor or “taste” is one of the most common persuasive marketing techniques used to promote food (mostly candy and snacks) to children on TV.²⁴ Exposure to ads for flavored products is positively associated with youth consumption,²⁵ and most money spent by youth is on food or beverages, particularly sweets.²⁶ Research on e-cigarettes comports with these findings, concluding: flavors play an important role for online e-cigarette marketing and boosts user interaction and positive emotion;²⁷ flavored (vs. unflavored) e-cigarette ads elicit greater appeal and interest in buying and trying e-cigarettes and the appeal of ads for flavors is linked to rapid and persistent adoption of e-cigarettes among youth;²⁸ and 75% of US youth stated they would not use e-cigarettes without flavors.²⁹

Youth are Attracted to Flavored Tobacco Products

The majority of youth in the US who try tobacco initiate with flavored tobacco products, including 81% of e-cigarette ever users, 65% of cigar ever users, and 50% of cigarette ever smokers.³⁰ Adolescents are more likely to report interest in trying an e-cigarette from a friend if it is menthol-, candy-, or fruit-flavored than if unflavored.³¹ Most adolescent current tobacco users cite flavors as a reason for use (including 81% for past 30-day e-cigarette users; 74% for past 30-day cigar users).¹⁰ Youth and young adult tobacco users are more likely than older adult tobacco users to use flavored products, including menthol cigarettes,³² flavored smokeless tobacco,³³ and flavored cigars.³⁴ Young smokers (12-17) are three times as likely to smoke menthol cigarettes as are smokers 35 and older.³⁵ Adolescents are more likely to report interest in trying an e-cigarette from a

Trinidad DR, Pérez-Stable EJ, Messer K, White MM, Pierce JP. Menthol cigarettes and smoking cessation among racial/ethnic groups in the United States. *Addiction*. 2010;105(SUPPL.1):84-94. doi:10.1111/j.1360-0443.2010.03187.x.

²³ Adkison SE, Bansal-Travers M, Smith DM, O'Connor RJ, Hyland AJ. Impact of smokeless tobacco packaging on perceptions and beliefs among youth, young adults, and adults in the U.S: findings from an internet-based cross-sectional survey. *Harm Reduct J*. 2014 Jan 17;11:2. doi: 10.1186/1477-7517-11-2.

²⁴ Jenkin G, Madhvani N, Signal L, Bowers S. A systematic review of persuasive marketing techniques to promote food to children on television. *Obesity reviews*. 2014;15(4):281-293.

²⁵ Cairns G, Angus K, Hastings G, Caraher M. Systematic reviews of the evidence on the nature, extent and effects of food marketing to children. A retrospective summary. *Appetite*. 2013;62:209-215.

²⁶ Kraak VI, Gootman JA, McGinnis JM. *Food marketing to children and youth: Threat or opportunity?* National Academies Press; 2006.

²⁷ Liang Y, Zheng X, Zeng DD, Zhou X. Impact of flavor on electronic cigarette marketing in social media. 2015:278-283.

²⁸ Vasiljevic M, Petrescu DC, Marteau TM. Impact of advertisements promoting candy-like flavoured e-cigarettes on appeal of tobacco smoking among children: An experimental study. *Tob Control*. 2016;25(e2):e107-e112.

²⁹ Zhu SH, Sun JY, Bonnevie E, et al. Four hundred and sixty brands of e-cigarettes and counting: Implications for product regulation. *Tob Control*. 2014;23 Suppl 3:iii3-9.

³⁰ Ambrose B, Day H, Rostron B, et al. Flavored tobacco product use among us youth aged 12-17 years, 2013-2014. *J Am Med Assoc*. 2015;314(17):1-3. doi:10.1001/jama.2015.13802.

³¹ Pepper JK, Ribisl KM, Brewer NT. Adolescents' interest in trying flavoured e-cigarettes. *Tob Control*. 2016;25(Suppl 2):ii62-ii66. doi:10.1136/tobaccocontrol-2016-053174.

³² Villanti AC, Mowery PD, Delnevo CD, Niaura RS, Abrams DB, Giovino GA. Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014. *Tob Control*. 2016;25(Suppl 2):ii14-ii20. doi:10.1136/tobaccocontrol-2016-053329.

³³ Oliver AJ, Jensen JA, Vogel RI, Anderson AJ, Hatsukami DK. Flavored and nonflavored smokeless tobacco products: Rate, pattern of use, and effects. *Nicotine Tob Res*. 2013;15(1):88-92. doi:10.1093/ntr/nts093.

³⁴ Delnevo CD, Giovenco DP, Ambrose BK, Corey CG, Conway KP. Preference for flavoured cigar brands among youth, young adults and adults in the USA. *Tob Control*. 2014;24(4):389-394. doi:10.1136/tobaccocontrol-2013-051408.

³⁵ Villanti AC, Mowery PD, Delnevo CD, Niaura RS, Abrams DB, Giovino GA. Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014. *Tob Control*. 2016:1-7. doi:10.1136/tobaccocontrol-2016-053329.

friend if it is menthol-, candy-, or fruit-flavored than if unflavored,³⁶ and three quarters of adolescent and young adult flavored tobacco product users reported they would quit if flavors were unavailable.³⁷

Flavors in smokeless tobacco enhance perceived product acceptability among youth and likely contribute to youth smokeless tobacco initiation and continued use

Smokeless tobacco products frequently feature the same sweeteners and chemical flavorings found in popular candies.³⁸ Most adolescent users of smokeless tobacco use flavored smokeless tobacco (69% of ever-users recall first starting with flavored smokeless tobacco; and 81% of current users now use flavored smokeless tobacco).³⁹ However, among adult (age 25+) smokeless tobacco current users, less than half use a flavored product.⁴⁰

Smokeless tobacco has a strong taste and odor. Potential and new users may need to overcome negative taste and sensation expectations before experimentation. Adding flavors to smokeless tobacco does just that. Adolescent users' preferences for flavored smokeless tobacco may relate to masking the tobacco taste or could correspond to stronger preferences for sweet flavors at younger ages.⁴¹

Tobacco industry documents show tobacco companies have a long history of adding flavors to smokeless tobacco products to increase youth appeal. The development of flavored smokeless tobacco products as starter products and the initiation steps in a "graduation" process was reported in the scientific literature decades ago.⁴² Further analyses of industry documents have shown that tobacco companies (including RJR) have a longstanding deep knowledge of the appeal of flavored smokeless tobacco and "candy brands" to young inexperienced tobacco users, that flavors and sugars both increase palatability and affect nicotine delivery of smokeless products, and mask the harsh and aversive effects of tobacco, facilitating youth initiation and continued use.⁴³

Beliefs regarding flavored smokeless tobacco are associated with youth susceptibility to smokeless tobacco use. Using data from the baseline wave of the nationally representative Population Assessment of Tobacco and Health (PATH) Youth Study, Chaffee et al. found US youth age 12-17 who had never tried any tobacco product (N=7,718) were more likely to report that flavored smokeless tobacco was "easier to use" compared to unflavored ST (20.2%) than to report that flavored smokeless tobacco was "harder to use" (5.8%).⁴⁴ Individuals

³⁶ Pepper JK, Ribisl KM, Brewer NT. Adolescents' interest in trying flavoured e-cigarettes. *Tob Control*. 2016;25(Suppl 2):ii62-ii66. doi:10.1136/tobaccocontrol-2016-053174.

³⁷ Loukas A, Jackson CD, Marti CN, Perry CL. Flavored tobacco product use among youth and young adults: What if flavors didn't exist? *Tob Regul Sci*. 2017;3(2):168-173.

³⁸ Miao S, Beach ES, Sommer TJ, Zimmerman JB, Jordt SE. High-Intensity Sweeteners in Alternative Tobacco Products. *Nicotine Tob Res*. 2016 Nov;18(11):2169-2173. doi: 10.1093/ntr/ntw141.

Brown JE, Luo W, Isabelle LM, Pankow JF. Candy flavorings in tobacco. *N Engl J Med*. 2014 Jun 5;370(23):2250-2. doi: 10.1056/NEJMc1403015.

³⁹ Ambrose BK, Day HR, Rostron B, Conway KP, Borek N, Hyland A, Villanti AC. Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014. *JAMA*. 2015 Nov 3;314(17):1871-3. doi: 10.1001/jama.2015.13802.

⁴⁰ Villanti AC, Johnson AL, Ambrose BK, Cummings KM, Stanton CA, Rose SW, Feirman SP, Tworek C, Glasser AM, Pearson JL, Cohn AM, Conway KP, Niaura RS, Bansal-Travers M, Hyland A. Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014). *Am J Prev Med*. 2017 Aug;53(2):139-151. doi: 10.1016/j.amepre.2017.01.026.

⁴¹ De Graaf C, Zandstra EH. Sweetness intensity and pleasantness in children, adolescents, and adults. *Physiol Behav*. 1999 Oct;67(4):513-20.

⁴² Connolly, Gregory N. "The Marketing of Nicotine Addiction by One Oral Snuff Manufacturer." *Tobacco Control* 4, no. 1 (1995): 73-79. <http://www.jstor.org/stable/20747349>.

⁴³ Kostygina G, Ling PM. Tobacco industry use of flavourings to promote smokeless tobacco products. *Tob Control*. 2016 Nov;25(Suppl 2):ii40-ii49. doi: 10.1136/tobaccocontrol-2016-053212.

who reported that flavored smokeless tobacco was easier to use were more likely to be susceptible to smokeless tobacco use than those who reported flavored smokeless tobacco was harder to use, about the same, or that they did not know. Susceptibility was measured using previously validated measures that have been shown to predict tobacco initiation about youth⁴⁵ - measures that ask youth to report their curiosity about smokeless tobacco and their willingness and expectations for future use. Adjusted for socio-demographic characteristics and other known tobacco initiation risk factors, such as receptivity to advertising, youth who viewed flavored smokeless tobacco as easier to use were at 1.5-times the odds of being susceptible to smokeless tobacco use than youth with any other perception regarding flavored smokeless tobacco and ease of use.

Couch et al. conducted a qualitative study examining with greater detail how flavors in smokeless tobacco potentially contribute to product appeal and initiation among youth. They interviewed 55 adolescent males at three rural high schools in the Western US, including 32 current or former users of smokeless tobacco. They found that particular flavors, packaging and other product characteristics appeared to enhance curiosity, experimentation, and peer acceptance of smokeless tobacco products.⁴⁶ Specifically, participants often associated flavored smokeless tobacco with appealing attributes of non-tobacco products, such as chewing gum, breath mints, food, and alcohol. When discussing smokeless tobacco flavors, one 17-year-old participant said, "It smelled good. So like, I thought, you know, maybe it will taste good, too. I mean, like I said, it was basically the same as gum."⁴⁷

Taken together, these findings show that flavors in smokeless tobacco are viewed favorably among adolescent smokeless tobacco users and potentially play a role in their motivation to initially try smokeless tobacco products and continue to use them. ***RJR ignored this evidence and failed to address how youth will perceive the flavors in the Snus products, that youth will perceive lower risk associated with Snus due to the flavors, and that such flavored Snus products will result in greater likelihood for initiation of Snus among non-users.***

Conclusion

When evaluating whether RJR should be allowed to market Snus as a MRTP, FDA must consider that adolescents who otherwise would not have used any tobacco product might find Snus appealing and will initiate using Snus as their first tobacco product. This is especially likely given adolescents' attraction to flavored tobacco products, the appeal of novel products among adolescents, and the tendency for the public at large, including adolescents, to misinterpret reduced harm claims.

Further, FDA must consider whether the evidence submitted by RJR were *independent studies*, and not studies that were conducted by RJR or influenced or paid by RJR.⁴⁸ In particular, FDA must review independent studies of adolescents' perceptions of Snus and the marketing claims made about Snus, as well as independent studies that examine whether in the real world adolescents are more or less likely to initiate with Snus compared to other tobacco products. FDA should review studies that examine adolescent consumers,' potential

⁴⁵ Pierce JP, Distefan JM, Kaplan RM, Gilpin EA. The role of curiosity in smoking initiation. *Addict Behav.* 2005 May;30(4):685-96.

Nodora J, Hartman SJ, Strong DR, Messer K, Vera LE, White MM, Portnoy DB, Choiniere CJ, Vullo GC, Pierce JP. Curiosity predicts smoking experimentation independent of susceptibility in a US national sample. *Addict Behav.* 2014 Dec;39(12):1695-700. doi: 10.1016/j.addbeh.2014.06.002.

⁴⁶ Couch ET, Darius EF, Walsh MM, Chaffee BW. ST product characteristics and relationships with perceptions and behaviors among rural adolescent males: a qualitative study. *Health Educ Res.* 2017 Dec 1;32(6):537-545. doi: 10.1093/her/cyx067.

⁴⁷ Couch ET, Darius EF, Walsh MM, Chaffee BW. ST product characteristics and relationships with perceptions and behaviors among rural adolescent males: a qualitative study. *Health Educ Res.* 2017 Dec 1;32(6):537-545. doi: 10.1093/her/cyx067.

⁴⁸ Institute of Medicine. 2012. *Scientific Standards for Studies on Modified Risk Tobacco Products.* Washington, DC: The National Academies Press. <https://doi.org/10.17226/13294>.

consumers,' and non-consumers' perceptions of Snus products, and their use in the real world. FDA must evaluate whether and to what extent adolescents initiate with Snus, whether they are likely to use both Snus and other tobacco products, and whether adolescents initiating with Snus will be more likely to subsequently initiate cigarette use. ***Because RJR did not submit with its MRTP application such rigorous, independent studies and because the application made no consideration of potential impact on adolescents, RJR did not meet its statutory burden under TCA section 911(g) to demonstrate that Camel Snus, as actually used by consumers, will benefit the health of the population as a whole, especially taking into account adolescents and other non-users. Therefore, FDA should deny RJR's MRTP application.***