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Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 2061
Rockville, MD 20852

RE: Modified Risk Tobacco Product Applications for Snus Products Submitted by Swedish Match North America, Inc., Docket No. FDA-2014-N-1051

The undersigned public health organizations submit these comments on the above-listed amended tobacco product modified risk applications submitted by Swedish Match North America, Inc. (“Swedish Match”) for multiple snus products (“General snus”). The amendments propose to make the following modified risk claim with respect to the General snus products: “Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.” The subject applications should be denied for the reasons detailed in these comments.

I. SUMMARY OF REASONS THE AMENDED GENERAL SNUS MODIFIED RISK APPLICATIONS SHOULD BE DENIED

The amended General Snus modified risk applications should be denied for the following reasons:

- **The applications should be denied for insufficient evidence on the impact of the marketing of General snus with modified risk claims on the increased likelihood of tobacco use initiation by non-users, particularly youth.**
 - Given the history of youth usage of smokeless tobacco and the current crisis of e-cigarette usage, and the statutory requirement for FDA to make a determination about the impact of a marketing order on youth, it is particularly important for FDA to require evidence that the marketing of General snus with modified risk claims will not increase youth initiation of tobacco products.
 - Without justification, Swedish Match has failed to present evidence on youth perception of the General snus modified risk claims.

- **The applications should be denied because the evidence indicates that the marketing of General snus with the proposed modified risk claims will lead to greater dual use with cigarettes instead of leading substantial numbers of smokers to switch completely to General snus.**
 - The experience with smokeless tobacco in the U.S. suggests that General snus, even with modified risk claims, will not cause substantial numbers of smokers to quit smoking and switch exclusively to General Snus.
 - The experience with smokeless tobacco in the U.S. suggests that the marketing of General snus with modified risk claims will lead to dual use.

- **The applications should be denied because Swedish Match has submitted insufficient evidence that its marketing will target only adult smokers and cause them to switch completely to General snus.**
 - The text of the proposed modified risk message does not adequately communicate to smokers that they must switch completely to reduce their health risks.
 - Swedish Match’s proposed marketing plan is not directed or limited to adult smokers and will still be seen by millions of youth.

- **Scandinavian epidemiological evidence is irrelevant to the expected experience in the U.S.**
 - Market differences in smokeless tobacco products available in Sweden and U.S. and the way the products are regulated may account for differences in snus use.
 - TPSAC’s conclusions about General snus in the Swedish Match proceeding provide no basis to believe the Swedish experience would be replicated in the U.S.

II. SUMMARY OF STATUTORY MODIFIED RISK STANDARDS

The General snus applications are governed by the standards set out in Section 911 of the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 (Section 911). Section 911 was enacted as a response to the tragic history of false and misleading tobacco industry claims that certain tobacco products were less

dangerous than other products that persuaded health-conscious smokers to switch to the “reduced risk” products instead of quitting altogether.

In enacting the Tobacco Control Act, Congress made specific findings about the potential harm to public health from modified risk claims that should guide FDA in its consideration of any modified risk product application. Congress found that “unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health. . . .” Sec. 2(37). Congress also found that “the dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk products are complete, accurate, and relate to the overall disease risk of the product.” Sec. 2(40). Congress determined that it is “essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will 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.” Sec. 2(36).

Under the Tobacco Control Act, a “modified risk tobacco product” is defined as a tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. A product is “sold or distributed” for such a use if, in relevant part,

(1) [its] label, labeling, or advertising, either implicitly or explicitly [represents] that

(i) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(ii) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(iii) the tobacco product or its smoke does not contain or is free of a substance, or

(3) . . . the tobacco product manufacturer has taken any action directed to consumers through the media or otherwise, other than by means of the label, labeling, or advertising. . . . that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or its free of, a substance or substances.

Thus, a modified risk product is defined in terms of the manufacturer's claims of reduced risk or reduced exposure in marketing the product, as well as its actions that may suggest to consumers that a product reduces risk or exposure to hazardous substances.

Under §911(g)(1), the burden is on the applicant seeking an order allowing the marketing of the product with a modified risk claim to demonstrate that the product "*as it is actually used by consumers* will (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." (emphasis added).

Sec. 911(g)(4) further requires FDA to take into account the following specific empirical factors in determining whether the (g)(1) standard has been met:

- (A) The relative health risks to individuals of the tobacco product that is the subject of the application;
- (B) The increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;
- (C) 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;
- (D) The risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence.

Thus, FDA must consider not only the effects of the asserted modified risk product on those who use it, but also its population-wide impact on tobacco use initiation, cessation and relapse, including an assessment of the likelihood that smokers would actually switch to the modified risk product. It is not enough for an applicant to show that the product is less hazardous to users than other tobacco products; in order for a modified risk application to be granted, the applicant is required to show that the benefits of risk reduction (considering the likelihood of smokers completely switching to the modified risk product) outweigh the risks of increased initiation or diminished cessation. In short, the statute requires FDA to make scientific judgments not only about the physical effect of the product's use, but also about the likely responses of potential consumers (both smokers and non-smokers) to the product's marketing as a modified risk product.

III. RELEVANT HISTORICAL BASIS FOR SECTION 911

FDA's application of the statutory standards set out in Section 911 must be mindful of the historical context that led Congress to enact those standards, particularly with respect to the Swedish Match applications for General snus.

The provisions of Section 911 were enacted in response to a massive evidentiary record of fraudulent health and "reduced risk" claims made by tobacco product manufacturers over the course of more than fifty years. Those claims caused millions of Americans to initiate cigarette smoking who otherwise would not have done so and caused millions of American smokers to continue smoking when they otherwise would have quit. In the absence of this massive industry fraud, literally millions of deaths, and untold suffering, would have been avoided.

The voluminous evidence of the industry's use of these false health-related claims was presented to the United States District Court for the District of Columbia in *United States v. Philip Morris, U.S.A., Inc.*¹ and furnished critical support for the court's conclusion that the defendant tobacco companies had engaged in a conspiracy to defraud the American public so massive as to constitute racketeering under federal law. A central component of the fraud was the representation of "light" and "low-tar" cigarettes as safer than other cigarettes, when the companies knew, as actually used by smokers, such cigarettes were no less hazardous. The court found:

Even as they engaged in a campaign to market and promote filtered and low tar cigarettes as less harmful than conventional ones, Defendants either lacked evidence to substantiate their claims or knew them to be false. Indeed, internal industry documents reveal Defendants' awareness by the late 1960s/early 1970s that, because low tar cigarettes do not actually deliver the low levels of tar and nicotine which are advertised, they are unlikely to provide any clear health benefit to human smokers, as opposed to the FTC smoking machine, when compared to regular, full flavor cigarettes.²

Thus, the industry defendants were found by the court to have violated civil racketeering laws in perpetrating decades-long fraudulent conduct that included the "light" and "low-tar" fraud.

In light of the tragic history of false and misleading reduced risk claims by the tobacco industry, FDA bears a special responsibility to ensure that the statutory standards, enacted by Congress to prevent a similar public health disaster from ever repeating itself, are rigorously applied to every modified risk tobacco application, including those submitted for General snus.

¹ 449 F. Supp.2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S.Ct. 3501 (2010).

² *Id.* at 430-31.

IV. THE APPLICATIONS SHOULD BE DENIED FOR INSUFFICIENT EVIDENCE ON THE IMPACT OF THE MARKETING OF GENERAL SNUS WITH MODIFIED RISK CLAIMS ON THE INCREASED LIKELIHOOD OF TOBACCO USE INITIATION BY NON-USERS, PARTICULARLY YOUTH

As noted above, in evaluating the General snus modified risk applications, FDA is required to determine whether granting the applications will lead to an “increased or decreased likelihood” that non-users of tobacco products will initiate use of General snus or some other tobacco product. Because initiation of tobacco products typically occurs when users are young, it is particularly important for FDA to assess the likelihood that the marketing of General snus with modified risk claims will lead to initiation by young people. Because the Swedish Match applications offer no evidence of youth perception of the proposed modified risk claims, they should be denied on that ground alone.

- A. Given the history of youth usage of smokeless tobacco and the current crisis of e-cigarette usage, it is particularly important for FDA to require evidence that the marketing of General snus with modified risk claims will not increase youth initiation of tobacco products.

When snus products were first introduced to the U.S. market, news reports indicated that they were popular among high school students because of their concealability. One news article from that time described a high school student admitting to using Camel snus during class, who said, “It’s easy, it’s super-discreet...and none of the teachers will ever know what I’m doing.”³ General snus is used in a similar manner as Camel snus, and so are easily concealed by youth. Given that smokeless tobacco rates among youth have not declined as rapidly as cigarette smoking,⁴ it is important that FDA require Swedish Match to produce data on the impact of expanding snus marketing with a modified risk message on youth initiation, including a possible gateway effect to smoking and dual use. Data on youth perception is particularly important since nothing in the Swedish Match marketing plans for General snus as modified risk products, which include print ads, radio and print media interviews and social media, provide assurance that youth will not be exposed to the modified risk claims.

The importance of FDA requiring data bearing on the likelihood of increased youth initiation prior to releasing its order on these modified risk applications is underscored by the current crisis of e-cigarette usage among young people, which both the Commissioner of the FDA,⁵ and the Surgeon General of the United States,⁶ have declared to have reached “epidemic”

³ Nelson, L, “If you think Snus is a safe alternative to smoking, think again,” *Kansas City Star*, October 31, 2007.

⁴ U.S. Centers for Disease Control and Prevention (CDC), “Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018,” *Morbidity and Mortality Weekly Report (MMWR)* 68(6):157–164, February 15, 2019, <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6806e1-H.pdf>.

⁵ Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency’s continued efforts to address growing epidemic of youth e-cigarette use, including potential new therapies to support cessation, November 2, 2018.

⁶ Surgeon General’s Advisory on E-Cigarette Use Among Youth, December 18, 2018 (SG Advisory).

proportions. Although there are obvious distinctions between e-cigarettes like JUUL and smokeless tobacco products like General snus, the fact that another kind of highly-addictive “reduced risk” product is proving so appealing to young people, in part because it can be used discreetly, should cause FDA to closely scrutinize the potential impact of modified risk claims for General snus on youth initiation.

Given the history of tobacco companies misleading the public on “light” and “low-tar” cigarettes, and marketing to youth to increase product sales, the worst-case scenario would be if youth and nonsmokers misunderstand the message and believe that General snus and other smokeless tobacco products are “safe” to start using, but then become addicted to nicotine and switch to smoking cigarettes or other combustible products.

In FDA’s briefing document to TPSAC on these amendments to Swedish Match’s application for General snus, the agency recommends “that the applicant monitor uptake by youth in its postmarket surveillance and studies and inform FDA immediately of any increases.”⁷ However, by then it may be too late. As we have experienced with e-cigarettes and youth, not only have prevalence rates skyrocketed, but health professionals are struggling with treating more and more youth for nicotine addiction, to the point that FDA has scheduled two workshops on the issue.⁸ Post-market surveillance may be too little, too late. It cannot be considered an adequate substitute for requiring the necessary data as part of the premarket review process for modified risk claims.

- B. Without justification, Swedish Match has failed to present evidence on youth perception of the General snus modified risk claims.

FDA should reject the Swedish Match applications because they provide no data whatsoever on youth perceptions of General snus as a modified risk product and no evidence regarding the potential for adolescent use. No accurate assessment of the impact on the health of the population as a whole can be made without consideration of actual data derived from studies of the perceptions of those under age 18. The total absence of data on youth perception of General snus, with the proposed modified risk claims, should—standing alone—preclude granting the Swedish Match applications. Indeed, the grant of these applications in the absence of that data would set the worst possible precedent and be wholly inconsistent with FDA’s statutory mission to protect the public health.

As noted above, FDA’s assessment of an MRTP application must consider the population-wide impact of the product on both users and non-users of tobacco products, which includes its impact on tobacco use initiation. Despite the fact that the effect of modified risk claims on underage users must be a central focus of FDA’s evaluation of an MRTP application,

⁷ FDA Briefing Document for TPSAC meeting, February 6-7, 2019 for MRTPAs by Swedish Match North America, Inc., at 28 (FDA Briefing Document).

⁸ 83 Fed Reg 64752-57. 84 Fed Reg 12619-21.

the Swedish Match MRTP applications provide no evidence whatsoever on the impact of the modified risk claims made for General snus on adolescent risk perception or adolescent use of tobacco products.

As FDA's Draft Guidance for the preparation of Modified Risk Tobacco Product Applications makes clear, FDA requires only that "all study subjects *receiving tobacco products* are current daily tobacco product users at least 21 years of age"⁹ (emphasis added). Not only is this limitation not applicable to studies of promotional material such as modified risk claims to determine the effect of such materials on adolescent risk perception or interest in using the product, but the 2012 Draft Guidance makes clear that inclusion of the effect on adolescent perception should be an essential feature of such studies. The Draft Guidance states:

To address the effect of the MRTP on tobacco use initiation, FDA recommends that applicants submit:

- Human studies that evaluate consumer perception of the product, including its labeling, marketing and advertising.

These studies should be designed to provide evidence regarding the likelihood of population benefit or harm from the proposed product, including...:

- The likelihood that consumers who have never used tobacco products, *particularly youth and young adults*, will initiate use of the tobacco product;¹⁰ (emphasis added)

Moreover, the Draft Guidance instructs companies to "estimate the attributable risk of all of the various health effects for various types of individuals in the U.S. population, as well as the total number of individuals of each type." The Draft Guidance goes on to state, "The types of individuals may include, but are not limited to, the following ... Non-users who initiate tobacco use with the proposed product, *such as youth*, never users, former users" (emphasis added).¹¹

Thus, far from prohibiting the testing of such messages on adolescents, the FDA Draft Guidance characterizes such testing as particularly important. In this light, the failure of Swedish Match to provide any evidence of the effect of these messages on adolescent risk perception is an inexplicable omission that ignores FDA's specific instruction to include that analysis.

Moreover, FDA's Draft guidance describes how such youth consumer perception research should be done. Recognizing that research among non-smokers, and non-smoking

⁹ FDA, Draft Guidance, Modified Risk Tobacco Applications, March 2012, at 29 (FDA 2012 Draft Guidance).

¹⁰ *Id.* at 20.

¹¹ *Id.* at 22.

youth in particular, requires care, FDA offered applicants an opportunity to work with the agency to determine the best way to conduct studies involving youth:

When designing consumer perception studies, applicants should take care that the studies themselves do not promote use of the product, particularly among vulnerable populations, such as youth, non-users of tobacco products, and pregnant women. FDA recommends that applicants meet with FDA to discuss research plans before embarking on research with vulnerable populations. Section IX.B of this guidance provides information on requesting a meeting with FDA.¹²

Swedish Match's failure to assess the impact of the marketing of General snus as a modified risk product on youth also contravenes recommendations made by the Institute of Medicine's (IOM) 2012 report, *Scientific Standards for Studies on Modified Risk Tobacco*, which recommended that "FDA should require studies to include populations of special relevance, including (but are not limited to) ... adolescents"¹³ and included an assessment of the effects on youth as "an essential element in establishing the public health benefit of an MRTP."¹⁴ The report included research on adolescents in three of its "Evidence domains relevant to an MRTP application."¹⁵ The need to consider the effects of promotional statements on youth is vitally important in light of the industry's documented history of marketing tobacco products in ways that attract adolescents and the role that youth initiation has played—and continues to play—in the recruitment of long-term adult smokers.¹⁶

According to IOM, perceptions of and intentions to use a given MRTP are also likely to differ by age group. Thus, IOM noted that it is "critical that studies include participants in the following age groups: children (≤ 12 years old), adolescents (13–17 years old), young or emerging adults (18–25 years old), adults (≥ 25 years old)."¹⁷ As noted by IOM, "adolescents' perceptions of the risks and benefits of cigarette smoking play an important role in adolescents' decisions to smoke. Given that adolescence is a period of heightened vulnerability for the initiation of tobacco use, it is important to evaluate whether adolescents accurately understand the purported benefits of an MRTP. Of particular importance are adolescents' perceptions of the risks and benefits of using

¹² *Id.* at 26.

¹³ Institute of Medicine, *Scientific Standards for Studies on Modified Risk Tobacco Products*, December 2011, at 14 (IOM report).

¹⁴ IOM report, at 50.

¹⁵ IOM report, at 7 (Summary).

¹⁶ U.S. Department of Health and Human Services (HHS), *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012, at 530-41, 603-27 and sources cited therein (2012 Surgeon General's Report); *U.S. v. Philip Morris*, 449 F. Supp. 2d, at 561-691.

¹⁷ IOM report, at 174.

the product, and whether they intend to initiate tobacco use with the MRTP rather than a traditional tobacco product because they believe the former is a “safe” alternative.”¹⁸

Similarly, the IOM report detailed ideas for how research on youth perceptions of risk of MRTPs can be conducted consistent with ethical standards of research.¹⁹ For example, IOM suggests that such research could be appropriately done under the supervision of an independent third party.²⁰ Such a procedure would make it possible for an applicant to develop evidence regarding the effect of the marketing of a product on this population. IOM noted that, “Survey research or perception/messaging research among non-smokers is acceptable where the non-smokers are not being exposed to the product.”²¹ Even in the case of studies that include exposure to a particular tobacco product among non-users (which is not critical in this case), IOM concluded, “Experimental research that exposes non-users to products is ethically problematic; but such research cannot completely be ruled out because it could provide critically valuable information. The ethics, risks, and benefits need to be determined on a case by case basis.”²²

Despite the express instructions in FDA’s Draft Guidance on the preparation of modified risk applications and the extensive discussion in the IOM report on how research on youth risk perception could appropriately be conducted, Swedish Match has submitted applications that ignore the effects of the proposed modified risk claims on youth. Applications that present no evidence on the effect of modified risk claims on youth initiation or perception of risk cannot possibly meet the public health standard.

Swedish Match’s failure to assess, in any way, the impact of its proposed modified risk message on youth is a particularly significant omission, given data indicating that smokeless tobacco use could be associated with future smoking for youth and young adults. One small study found an association between snus use among non-smoking youth and young adults and increased likelihood of cigarette smoking initiation, current cigarette smoking, and more intense cigarette smoking two years later.²³ Though the proportions from the study are small, those findings are supported by older studies linking smokeless tobacco use to later cigarette smoking.²⁴ More recently, a study using data from the Population Assessment of Tobacco and

¹⁸ IOM report, at 165.

¹⁹ IOM report, at 10.

²⁰ IOM report, at 57.

²¹ IOM report, at 52.

²² IOM report, at 52-53.

²³ Soneji, S, et al., “Associations Between Initial Water Pipe Tobacco Smoking and Snus Use and Subsequent Cigarette Smoking Results from a Longitudinal Study of US Adolescents and Young Adults,” *JAMA Pediatrics* 169(2):129-136, 2015.

²⁴ Tomar, SL, et al., “Is Smokeless Tobacco Use an Appropriate Public Health Strategy for Reducing Societal Harm?,” *International Journal of Environmental Research and Public Health* 6:10-24, 2009, at 16. Severson, H, et al., “Use of smokeless tobacco is a risk factor for cigarette smoking,” *Nicotine and Tobacco Research* 9(12):1331-1337, December 2007. Haddock, CK, et al., “Evidence that smokeless tobacco use is a gateway for smoking initiation in young adult males,” *Preventive Medicine* 32:262-267, 2001. Tomar, S, “Snuff Use and Smoking in U.S. Men: Implications for Harm Reduction,” *American Journal of Preventive Medicine* 23(3):143-149, October 2002. Tomar, S, “Is use of smokeless tobacco a risk factor for cigarette smoking? The U.S. experience,” *Nicotine &*

Health (PATH) study found that non-smoking youth (12-17 years old) using smokeless tobacco (including snus) at baseline had higher odds of cigarette smoking initiation and two times the odds of past 30-day cigarette smoking at follow-up a year later compared to non-users.²⁵ A systematic review study cited by FDA in its Briefing Document to TPSAC on the Camel snus modified risk applications found that between 16.6% to 25.5% of adolescent exclusive smokeless tobacco users transitioned to exclusive cigarette smoking within a handful of years.²⁶

This pattern is not isolated to the U.S.: a study from Norway found that age may be a factor in transitioning from snus to cigarettes. It found that people who started using snus before 16 years old were much more likely to become adult smokers compared to those who started snus later.²⁷

Moreover, initial smokeless tobacco use is also associated with later multiple tobacco product use. A survey of adolescents and young adults who had ever used tobacco found that those who initiated any tobacco use with smokeless tobacco (or any other non-combustible product) had higher odds of using multiple tobacco products than those who initiated with a combustible product.²⁸

Therefore, Swedish Match's failure to develop and submit any data whatsoever on youth perceptions of the proposed modified risk messages is sufficient, by itself, to support denial of the applications.

V. THE APPLICATIONS SHOULD BE DENIED BECAUSE THE EVIDENCE INDICATES THAT THE MARKETING OF GENERAL SNUS WITH THE PROPOSED MODIFIED RISK CLAIMS WILL LEAD TO GREATER DUAL USE WITH CIGARETTES INSTEAD OF LEADING SUBSTANTIAL NUMBERS OF SMOKERS TO SWITCH COMPLETELY TO GENERAL SNUS

- A. The experience with smokeless tobacco in the U.S. suggests that General snus, even with modified risk claims, will not cause substantial numbers of smokers to quit smoking and switch exclusively to General snus.

Tobacco Research 5(4):561-569, August 2003, <http://www.ncbi.nlm.nih.gov/pubmed/12959794>. See also, Tomar, SL, "Smokeless tobacco use is a significant predictor of smoking when appropriately modeled," *Nicotine & Tobacco Research* 5(4):571-573, August 2003, <http://www.ncbi.nlm.nih.gov/pubmed/12959795>.

²⁵ 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 Pediatrics* 172(2):181-187, 2018.

²⁶ Tam, J, et al., "A systematic review of transitions between cigarette and smokeless tobacco product use in the United States," *BMC Public Health* 15:258, 2015. See also, FDA Briefing Document for TPSAC meeting, Sept. 13-14, 2018 for MRTPAs by R.J. Reynolds Tobacco Co., at 61

²⁷ Lund, I & Scheffels, J, "Smoking and Snus Use Onset: Exploring the Influence of Snus Debut Age on the Risk for Smoking Uptake With Cross-Sectional Survey Data," *Nicotine & Tobacco Research* 16(6):815-819, 2014.

²⁸ Soneji, S, Sargent, J, & Tanski, S, "Multiple tobacco product use among US adolescents and young adults," *Tobacco Control*, 2014, [Epub ahead of print], <http://www.ncbi.nlm.nih.gov/pubmed/25361744>.

General snus currently has relatively low use rates in the U.S. compared to traditional smokeless tobacco products. Swedish Match has not provided sufficient evidence that a modified risk designation will increase its use by smokers who plan to switch completely, or if those smokers will use General snus in addition to smoking cigarettes. In fact, a study of U.S. smokers who were interested in quitting smoking with oral tobacco products showed that smokers did not like General snus and did not choose to use it during the study period.²⁹ As discussed in our past comments to Swedish Match’s General snus modified risk docket³⁰ and those filed before TPSAC in January 2019,³¹ data generally do not show that smokers will use smokeless tobacco products, including snus, to quit smoking, and that the opposite trend (smokeless tobacco to cigarette smoking) is more likely. The 2008 Update of the U.S. Public Health Service Clinical Practice Guidelines regarding tobacco cessation concluded, “the use of smokeless tobacco products is not a safe alternative to smoking, nor is there evidence to suggest that it is effective in helping smokers quit.”³² Thus, there is reason to doubt, based on available U.S. data, experiences, alternative products on the market, and current regulatory structures, that U.S. smokers will actually switch completely to General snus, even with the proposed modified risk claim.

In its briefing document to TPSAC in February 2019, FDA found several deficiencies in the research submitted by Swedish Match that makes it difficult to conclude whether or not adult smokers would completely switch to General snus, given the modified risk messaging: “The applicant did not submit evidence that smokers would use General Snus as a complete substitute for smoking. Among current smokers, adding the proposed claim to the video advertisement did not affect intentions to quit smoking. However, it is unknown whether adding the proposed claim may have increased or decreased intentions to quit smoking among the subset of smokers who became more likely to buy General Snus after viewing the proposed claim, as the applicant’s research was not designed to assess this. The applicant’s research also did not assess intended patterns of use (e.g., intended frequency; intentions to dual use with cigarettes) among participants who indicated that they were likely to buy General Snus.”³³

²⁹ Hatsukami, DK, et al., “Oral tobacco products: preference and effects among smokers,” *Drug and Alcohol Dependence* 118(2-3):230–236, 2011.

³⁰ See e.g., Comments of Campaign for Tobacco-Free Kids and Tobacco Control Legal Consortium in Docket No. FDA-2014-N-1951, Modified Risk Applications for 10 Products Submitted by Swedish Match North America, Inc. (November 25, 2014), at 27-29; Comments of Campaign for Tobacco-Free Kids and Tobacco Control Legal Consortium in Docket No. FDA-2014-N-1051, Reopening of Comments Period for Modified Risk Tobacco Product Applications: Applications for 10 Products Submitted by Swedish Match North America, Inc. (August 25, 2015).

³¹ Comments of Campaign for Tobacco-Free Kids in Docket No. FDA-2014-N-1051, Tobacco Products Scientific Advisory Committee meeting on amendments to Modified Risk Tobacco Product Applications for Snus Products Submitted by Swedish Match North America Inc. (January 22, 2019).

³² Fiore, MC, et al., *Treating Tobacco Use and Dependence: 2008 Update*, U.S. Public Health Service Clinical Practice Guideline, May 2008, http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.

³³ FDA Briefing Document for TPSAC meeting, February 6-7, 2019 for MRTPAs by Swedish Match North America, Inc., at 27 (FDA Briefing Document).

- B. The experience with smokeless tobacco in the U.S. suggests that the marketing of General snus with modified claims will lead to dual use.

Smokers may try snus for various reasons, including to reduce their smoking, but they more often end up using both products rather than switching completely.³⁴ Studies from the years before e-cigarettes became popular show an increase dual use of smokeless tobacco and cigarettes.³⁵ Data from the NIH and FDA-funded Population Assessment of Tobacco and Health (PATH) study from 2013-2014 survey found that 42.6 percent of adult cigarette smokers were snus users, compared to 27.7 percent of former smokers and 29.7 percent of never smokers who reported currently using snus.³⁶ Minnesota Adult Tobacco survey data show that the increase in smokeless tobacco use was largely due to current smokers using smokeless tobacco concurrently, not to smokers switching to smokeless tobacco.³⁷

Survey data also show that multiple tobacco product use is common among youth and adult tobacco users,³⁸ and before e-cigarettes, dual use of smokeless tobacco and cigarettes was popular.³⁹ Data from the 2013-2014 PATH study found that there were more current snus users also using other tobacco products than exclusive snus users.⁴⁰ Moreover, snus users were “more likely to report...polytobacco use than users of other SLT [smokeless tobacco] products.”⁴¹

While *complete switching* to snus might “significantly” or “greatly” reduce smokers’ risk of certain smoking-related diseases, incomplete switching (dual use or merely cutting down smoking) keeps smokers’ risks of disease elevated.⁴² A substantial body of evidence supports

³⁴ Biener L, et al., “Snus Use and Rejection in the United States,” *Tobacco Control* 25(4):386-392, 2016, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4519419/pdf/nihms707341.pdf>.

³⁵ Rath, JM, et al., “Patterns of Tobacco Use and Dual Use in US Young Adults: The Missing Link between Youth Prevention and Adult Cessation,” *Journal of Environmental and Public Health* 2012(679134):1-9, 2012, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3361253/pdf/JEPH2012-679134.pdf>. Boyle, R, et al., “Concurrent Use of Cigarettes and Smokeless Tobacco in Minnesota,” *Journal of Environmental and Public Health*, 2012.

³⁶ Cheng, Y, et al., “Patterns of Use of Smokeless Tobacco in US Adults, 2013–2014,” *American Journal of Public Health* 107(9):1508-1514, 2017, at 1513.

³⁷ Boyle, R, et al., “Concurrent Use of Cigarettes and Smokeless Tobacco in Minnesota,” *Journal of Environmental and Public Health*, (2012).

³⁸ Kasza, KA, et al., “Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014,” *New England Journal of Medicine* 376(4):342-353, 2017.

³⁹ Substance Abuse and Mental Health Services Administration (SAMHSA), *The NSDUH Report: Smokeless Tobacco Use, Initiation, and Relationship to Cigarette Smoking: 2002 to 2007*, Rockville, MD: Office of Applied Studies, March 5, 2009, at 5. Tomar, SL, “Patterns of Dual Use of Cigarettes and Smokeless Tobacco among U.S. Males: Findings from National Surveys,” *Tobacco Control* 19:104-109, 2010, at 105. Rath, JM, et al., “Patterns of Tobacco Use and Dual Use in US Young Adults: The Missing Link between Youth Prevention and Adult Cessation,” *Journal of Environmental and Public Health* 2012(679134):1-9, 2012, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3361253/pdf/JEPH2012-679134.pdf>.

⁴⁰ Cheng, Y, et al., “Patterns of Use of Smokeless Tobacco in US Adults, 2013–2014,” *American Journal of Public Health* 107(9):1508-1514, 2017.

⁴¹ Cheng, Y, et al., “Patterns of Use of Smokeless Tobacco in US Adults, 2013–2014,” *American Journal of Public Health* 107(9):1508-1514, 2017.

⁴² U.S. Department of Health and Human Services (HHS), *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease*, U.S. Centers for Disease Control and Prevention (CDC), Office of Smoking and Health (OSH), 2010, at 9. HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report*

the proposition that health benefits to an individual from quitting smoking occur only if the individual completely quits smoking. A newly published study found that “potential harm reduction can only be realized if smokers are instructed to stop smoking and completely switch to snus; partial reduction in smoking has minimal effects on biomarkers of exposure.”⁴³

Merely reducing the number of cigarettes smoked or engaging in dual use of cigarettes and other tobacco products does not substantially reduce the health risk, as several U.S. Surgeon General’s Reports and other studies have indicated that the risk of cardiovascular disease and other smoking-related diseases depends largely on the length of time a person smokes, not the number of cigarettes smoked.⁴⁴ According to the CDC, “If you only cut down the number of cigarettes you smoke by adding another tobacco product...you still face serious health risks. Smokers must quit smoking completely to fully protect their health – even a few cigarettes a day are dangerous.”⁴⁵

Studies show that dual use can increase health risks because of continued smoking or perhaps added exposure from snus. An older study concluded, “Because the health risks associated with cigarettes and ST are different in some respects, and because their effects may be additive if not synergistic, the concomitant use of cigarettes and ST may increase the risk of tobacco-attributable death and disease relative to use of either product alone.”⁴⁶ A study from 2017 determined that reporting health issues was more likely among people who used both smokeless tobacco and cigarettes compared to those who used only one product.⁴⁷

of the Surgeon General, CDC, OSH, 2012, at 22, <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html>. Schane, RE, Ling, PM, & Glantz, SA, “Health Effects of Light and Intermittent Smoking: A Review,” *Circulation* 121(3):1518-1522, 2010. Tverdal, A & Bjartveit, K, “Health Consequences of Smoking 1-4 Cigarettes per Day,” *Tobacco Control* 14(5), 2005. Hackshaw, A, et al., “Low cigarette consumption and risk of coronary heart disease and stroke: meta-analysis of 141 cohort studies in 55 study reports,” *BMJ* 360:j5855, <http://doi.org/10.1136/bmj.j5855>, 2018.

⁴³ Meier, E, et al., “A Randomized Clinical Trial of Snus Examining the Effect of Complete Versus Partial Cigarette Substitution on Smoking-Related Behaviors, and Biomarkers of Exposure,” *Nicotine & Tobacco Research*, Advanced Access, April 11, 2019.

⁴⁴ U.S. Department of Health and Human Services (HHS), *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease*, U.S. Centers for Disease Control and Prevention (CDC), Office of Smoking and Health (OSH), 2010, at 9. HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, CDC, OSH, 2012, at 22, <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html>. Schane, RE, Ling, PM, & Glantz, SA, “Health Effects of Light and Intermittent Smoking: A Review,” *Circulation* 121(3):1518-1522, 2010. Tverdal, A & Bjartveit, K, “Health Consequences of Smoking 1-4 Cigarettes per Day,” *Tobacco Control* 14(5), 2005. Hackshaw, A, et al., “Low cigarette consumption and risk of coronary heart disease and stroke: meta-analysis of 141 cohort studies in 55 study reports,” *BMJ* 360:j5855, <http://doi.org/10.1136/bmj.j5855>, 2018.

⁴⁵ CDC, “Powerful new Tips from Former Smokers” ads focus on living with vision loss and colorectal cancer,” CDC Press Release, March 26, 2015, <http://www.cdc.gov/media/releases/2015/p0326-tips.html>. See also: CDC, “Dual Use of Tobacco Products.” <http://www.cdc.gov/tobacco/campaign/tips/diseases/dual-tobacco-use.html#ten>.

⁴⁶ Wetter, D, et al., “Concomitant Use of Cigarettes and Smokeless Tobacco: Prevalence, Correlates, and Predictors of Tobacco Cessation,” *Preventive Medicine* 34:638-648, 2002.

⁴⁷ Hernandez, SL, et al., “Relationships Among Chewing Tobacco, Cigarette Smoking, and Chronic Health Conditions in Males 18–44 Years of Age,” *Journal of Primary Prevention* 38(5):505-514, 2017.

In addition to the potential additive health risks, dual use may keep smokers smoking longer, which also continues to elevate their health risks. Several studies have found that dual users have similar or lower likelihood of quitting or attempting to quit smoking compared to exclusive cigarette smokers.⁴⁸ One study has found that, while dual users were more likely to make a quit attempt compared to exclusive smokers, they tended to relapse more quickly compared to exclusive smokers, and had comparable 30-day abstinence levels to exclusive smokers.⁴⁹ Dual users of smokeless tobacco and cigarettes use smokeless tobacco to maintain their cigarette addiction, not to quit smoking,⁵⁰ and do not believe that smokeless products can help them quit smoking.⁵¹ One study found that smokeless users who used these products to cut down on smoking were no more likely to stop using cigarettes compared to those smokers who did not use smokeless tobacco,⁵² and another study found that smokers saw these products as temporary, rather than complete substitutes.⁵³

Because of the critical difference in health outcomes for those who completely quit smoking when they take up snus and those who use cigarettes and snus concurrently, it is essential that any modified risk claims for snus include clear and understandable statements to consumers advising them that any health benefits depend upon their switching entirely away from cigarettes.

⁴⁸ Schauer, GL, Pederson, LL, & Malarcher, AM, “Past Year Quit Attempts and Use of Cessation Resources Among Cigarette-Only Smokers and Cigarette Smokers Who Use Other Tobacco Products,” *Nicotine & Tobacco Research* 18(10):41-47, 2016. Klesges, RC, et al., “Tobacco Use Harm Reduction, Elimination, and Escalation in a Large Military Cohort,” *American Journal of Public Health* 100(12):2487-2492, December 2010, at 2490 (“Importantly, dual users were less likely to become tobacco abstinent than were smokers or smokeless tobacco users . . .”); Wetter, D, et al., “Concomitant Use of Cigarettes and Smokeless Tobacco: Prevalence, Correlates, and Predictors of Tobacco Cessation,” *Preventive Medicine* 34:638-648, 2002, (“Concomitant users were significantly less likely to quit using tobacco over the course of 4 years than were users of cigarettes or ST.”).

⁴⁹ Messer, K, et al., “Cigarette smoking cessation attempts among current US smokers who also use smokeless tobacco,” *Addictive Behaviors* 51:113-119, 2015.

⁵⁰ McClave-Regan, AK & Berkowitz, J, “Smokers who are also using smokeless tobacco products in the US: a national assessment of characteristics, behaviours and beliefs of ‘dual users’,” *Tobacco Control* 20:239-242, 2011, <http://www.ncbi.nlm.nih.gov/pubmed/21172853>.

⁵¹ McClave-Regan, AK & Berkowitz, J, “Smokers who are also using smokeless tobacco products in the US: a national assessment of characteristics, behaviours and beliefs of ‘dual users’,” *Tobacco Control* 20:239-242, 2011.

⁵² Kasza, KA, et al., “Cigarette Smokers’ Use of Unconventional Tobacco Products and Associations With Quitting Activity: Findings From the ITC-4 U.S. Cohort,” *Nicotine & Tobacco Research* 16(6):672-681, June 2014, <http://www.ncbi.nlm.nih.gov/pubmed/24376276>.

⁵³ O’Connor, RJ, et al., “US smokers’ reactions to a brief trial of oral nicotine products,” *Harm Reduction Journal* 8:1-10, 2011, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3032705/pdf/1477-7517-8-1.pdf>.

VI. THE APPLICATIONS SHOULD BE DENIED BECAUSE SWEDISH MATCH HAS SUBMITTED INSUFFICIENT EVIDENCE THAT ITS MODIFIED RISK MESSAGE WILL CAUSE SMOKERS TO SWITCH COMPLETELY AND THAT ITS MARKETING WILL TARGET ONLY ADULT SMOKERS

- A. The text of the proposed modified risk message does not adequately communicate to smokers that they must switch completely to reduce their health risks.

As currently proposed, the language in Swedish Match's claim does not communicate to consumers that a health benefit can be realized only by completely switching from cigarettes to snus. The use of the term "instead" could be interpreted to mean that a smoker can lower his/her risk of the listed diseases simply by substituting General snus for some cigarette smoking, without not switching entirely from cigarettes to General snus. However, since consumers only derive benefits from General snus if they completely switch from cigarettes to General snus, the claim proposed by Swedish Match is inadequate.

In amendments submitted on October 24, 2018 in response to questions from FDA, data from Swedish Match indicate that, even after viewing the proposed modified risk message in a video, adult smokers did not fully understand that they had to completely stop using cigarettes to reduce one's risk with General snus. Among legal age (per state) to 24 year olds exposed to the modified risk message, a little more than half (56.2%) of respondents correctly responded "zero (0) cigarettes" when asked to identify the "number of cigarettes one can smoke a day for General Snus to lower risk of disease. While this percentage was higher than in the control group, which did not see the modified risk claim, it was not much better – 45.0% among the control group answering "zero (0) cigarettes" versus the aforementioned 56.2%. In addition, 15.6% answered with some number of cigarettes (including 8.6% selecting "as many as you want to smoke"), and 28.1% answered "none of the above" or "don't know," showing a considerable degree of misunderstanding even after exposure to the modified risk claim.

The answers among older adults exposed to the modified risk claim were even more troubling, with less than half (43.7%) of adult smokers over 24 years old answering "zero (0) cigarettes," 14.4% responding with some number of cigarettes, and 42.1% answering "none of the above" or "don't know." Although Swedish Match's proposed modified risk messages might indicate to some smokers that they cannot use cigarettes with General snus to lower one's disease risk, a substantial percentage of smokers still do not understand the importance of completely switching after exposure to the messaging.

- B. Swedish Match's proposed marketing plan is not directed or limited to adult smokers and will still be seen by millions of youth.

In public statements, Swedish Match claims its “goal is to eliminate cigarette use,”⁵⁴ yet the proposed marketing plan in these applications does not describe any strategies that would minimize exposure to these claims by non-smokers, or even focus strictly on adult cigarette smokers.

Swedish Match has proposed using the modified risk messaging on its branded website, in print and online advertising, in direct mail and email communications, in social media websites, at events with consumer engagements, and in earned media or public relations opportunities. As noted above, Swedish Match’s proposed modified risk claim is as follows: “Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.” By its terms, this claim is not directed exclusively at smokers. Moreover, nothing in the General snus amendments indicates that only adult smokers will be exposed to the claim.

There is certainly a risk that the print and online advertisements proposed by Swedish Match⁵⁵ could be seen by tobacco users and non-tobacco users alike and could induce non-tobacco users to try snus. Studies have found that tobacco companies have violated the provision of the Master Settlement Agreement between the major cigarette companies and the states requiring the participating companies that limits their print marketing to magazines with 85% adult readership and no more than 2 million youth readers.⁵⁶

Swedish Match indicates its intention to include the proposed modified risk claim in messages to its list of recipients for General snus emails and direct mail.⁵⁷ These recipients are presumably existing General snus users, not necessarily smokers who could benefit from an effective modified risk message. For existing snus users, the modified risk message may simply encourage them to continue their use, with the resulting disease risk, when they otherwise may have quit tobacco use entirely. In any event, Swedish Match can hardly claim that its modified risk message will be confined to adult smokers.

⁵⁴ Swedish Match website, “Improve Public Health,” accessed April 26, 2019 from <https://www.swedishmatch.com/Sustainability/improve-public-health/>.

⁵⁵ Swedish Match, MRTPA Response to Advice/Information Request, October 24, 2018, at 13.

⁵⁶ Massachusetts Department of Health, “Smokeless Tobacco Advertising Expenditures Before and After the Smokeless Tobacco Master Settlement Agreement,” May 2002. King, C & Siegel, M, “The Master Settlement Agreement with the Tobacco Industry and Cigarette Advertising in Magazines,” *New England Journal of Medicine* 345(7):504-511, August 16, 2001. Bowker, D & Hamilton, M, “Cigarette Advertising Expenditures before and After the Master Settlement Agreement: Preliminary Findings,” May 15, 2000.

⁵⁷ Swedish Match, MRTPA Response to Advice/Information Request, October 24, 2018, at 15-17.

VII. SCANDINAVIAN EPIDEMIOLOGICAL EVIDENCE IS IRRELEVANT TO THE EXPECTED EXPERIENCE IN THE U.S.

- A. Market differences in smokeless tobacco products available in Sweden and U.S. and the way the products are regulated may account for differences in snus use.

Because Swedish snus has been widely used in Sweden for many years, and because snus has constituted the vast majority of smokeless tobacco used in Sweden for many years, there exists a large data set for the evaluation of the health effects of Swedish snus in comparison with the health effects of cigarettes in Sweden.

It is important to note, however, that this experience exists only with respect to health outcomes in Scandinavia involving the use of Swedish snus itself. Because the smokeless tobacco marketplace in the U.S. is so different than in Scandinavian countries, the attractiveness of General snus, even with the modified risk messages, likely would not resemble the use patterns in Sweden. For instance, the popular smokeless tobacco products in the U.S. are traditional moist snuff, not snus. The overall snus market in the U.S. is quite low compared to other moist snuff products. Convenience store data show that spitless tobacco products, including snus, made up less than six percent of smokeless tobacco unit sales through 2018.⁵⁸

In addition, e-cigarettes are now readily available in the U.S., and e-cigarette use is higher than snus (or smokeless tobacco) use among youth and adults.⁵⁹ Any consideration of General snus modified risk messages needs to account for the presence of e-cigarettes as another alternative to smoking.

Finally, it is worth noting that much of the type of marketing in which Swedish Match is seeking to engage in the U.S. is not even allowed in Sweden. Tobacco advertising in most media such as print advertisements and outdoor signage is not permitted in Sweden, though Internet and some point-of-sale advertising are allowed.⁶⁰ Indeed, Sweden has achieved high use rates for snus even without using the types of modified risk messages that Swedish Match has proposed. This difference may well account for distinctions in the way snus is used in Sweden, where most

⁵⁸ “Tobacco: OTP,” *Convenience Store/Petroleum Category Management Handbook* 2019, https://www.qgdigitalpublishing.com/publication/?i=580380#{%22issue_id%22:580380,%22page%22:46}, at 45, 46.

⁵⁹ CDC, “Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018,” *Morbidity and Mortality Weekly Report (MMWR)* 68(6):157-164, February 15, 2019, <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6806e1-H.pdf>. Current use defined as any use in the past 30 days. CDC, “Tobacco Product Use Among Adults — United States, 2017,” *MMWR* 67(44):1225-1232, November 9, 2018, <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6744a2-H.pdf>.

⁶⁰ 14-14b §§ Tobakslag [Tobacco Act] (Svensk författningssamling [SFS] 1993:581) (Swed.), available at <http://rkrattsbaser.gov.se/sfst?bet=1993:581>. English version available at <https://www.tobaccocontrol.org/files/live/Sweden/Sweden%20-%20SFS%202010727.pdf>.

use it exclusively,⁶¹ as compared to how it has been used in the United States, with higher dual use rates.⁶²

In the U.S., many new smokeless tobacco products have been marketed as a way to get a nicotine fix when smokers cannot smoke, and Swedish Match is no exception. In examples of marketing outreach submitted to FDA in its November 26, 2018 amendment, Swedish Match included an email sent in September 2018 that stated, “The tobacco experience you can enjoy anywhere.”⁶³ This messaging echoes statements used by other tobacco companies in marketing their snus products, to indicate that these products can be used as temporary substitutes in places where cigarette smoking is not allowed. Previous examples show that Swedish Match has used similar messaging before. In its magazine promoting General snus, *Elevation*, an ad states, “With General snus, there’s no smoke, no spit and no limit to where you can go. So no matter where you’re off to next, pack the tobacco that helps you embrace any adventure, anywhere.”⁶⁴ Such marketing discourages smokers from taking the one step that is sure to protect their health, which is to quit smoking entirely. Given what is known about current use patterns and marketing strategies, engaging in marketing practices that are already common in the U.S. may not lead to use rates seen in Sweden.

- B. TPSAC’s conclusions about General snus in the Swedish Match proceeding provide no basis to believe the Swedish experience would be replicated in the U.S.

The original modified risk applications filed by Swedish Match and the General snus amendments rely heavily on the experience with snus in Scandinavian countries, particularly Sweden, in assessing the likely behavioral impact in the U.S. of marketing General snus as modified risk products. The relevance of the Swedish experience is discussed extensively in previous submissions by the Campaign for Tobacco-Free Kids in this Docket, and in the Docket established in connection with the R.J. Reynolds modified risk application for Camel snus, which are incorporated by reference.⁶⁵ As those submissions argue, there are substantial reasons to be

⁶¹ Lund, KE & McNeill, A, “Patterns of Dual Use of Snus and Cigarettes in a Mature Snus Market,” *Nicotine & Tobacco Research* 15(3):678-684, 2013.

⁶² Cheng, Y, et al., “Patterns of Use of Smokeless Tobacco in US Adults, 2013–2014,” *American Journal of Public Health* 107(9):1508-1514, 2017. Lund, KE, McNeill, A, & Scheffels, J, “The use of snus for quitting smoking compared with medicinal products,” *Nicotine & Tobacco Research* 12(8):817-22, August 2010,

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2910876/pdf/ntq105.pdf>. Tomar, S, Alpert, HR, & Connolly, GN, “Patterns of Dual Use of Cigarettes and Smokeless Tobacco Among US Males: Findings from National Surveys,” *Tobacco Control* 19:104-109, 2010, <http://tobaccocontrol.bmj.com/content/19/2/104.full.pdf+html>. Agaku, IT, et al., “Use of Conventional and Novel Smokeless Tobacco Products Among US Adolescents,” *Pediatrics* 132(3):e578-86, September 2013, <http://pediatrics.aappublications.org/content/early/2013/07/31/peds.2013-0843.full.pdf>.

⁶³ Swedish Match amendment, Appendix 1, FDA Registration Brand Consumer Communications, November 26, 2018, at 17.

⁶⁴ General snus ad in *Elevation* magazine, 2017, available at <http://www.trinketsandtrash.org/detail.php?artifactid=12362>.

⁶⁵ See e.g. Comments of Campaign for Tobacco-Free Kids and Tobacco Control Legal Consortium in Docket No. FDA-2014-N-1951, Modified Risk Applications for 10 Products Submitted by Swedish Match North America, Inc.

skeptical of the Swedish experience as a predictive guide to the likely population-wide impact of marketing General snus in the U.S. as modified risk tobacco products.

It should also be noted that TPSAC already has considered the relevance of the Swedish experience to the assessment of the impact of Swedish snus as modified risk products in the U.S. Thus, in its April, 2015 meeting on the Swedish Match modified risk applications, TPSAC voted on two issues relating to the relevance of the Swedish data. The key votes on these issues were as follows:

1. Does the Committee believe that the epidemiological data from Sweden concerning tobacco use behavior provide relevant information on the likelihood that current tobacco users in the U.S. will switch to the use of these snus products? **TPSAC voted 6 votes “no,” 1 vote “yes” and 1 abstention.**
2. Does the Committee believe that the epidemiological data from Sweden concerning tobacco use behavior provide relevant information on the likelihood that non-users of tobacco in the U.S. will initiate the use of these snus products? **TPSAC answered “no” by of vote of 5 votes “no” with 3 abstentions.**

In order to evaluate the relevance of the behavior of individuals in different countries, it is necessary to take into account differences in culture, history, prior experience, laws and rules. There is no scientific basis to conclude that, because the population in one country responded to a product, or to how a product was marketed, in a particular way, that the population of another country will respond similarly. In light of the limitations noted by TPSAC and FDA on the use of Swedish data to predict the likely usage of snus modified risk products in the U.S., FDA’s decision, in its recent PMTA order on IQOS, to rely exclusively on data from Japan and Italy in concluding that “the current evidence indicates low IQOS uptake by youth” in the U.S.⁶⁶ is, by any reasonable standard, arbitrary and impossible to defend from a scientific standpoint.

In fact, the FDA social science review of the IQOS application yielded “concerns with respect to: the lack of information about youth under age 18, as well as the lack of a discussion of submitted data’s applicability to youth and the lack of presentation of the data in stratified categories that would allow us to make inferences about youth”⁶⁷ Nevertheless, the Technical Project Lead disagreed with these concerns, relying entirely on data from Japan and Italy in predicting low youth IQOS uptake in the U.S., with no analysis of possible differences between the U.S. and those countries in their tobacco product markets, cultural factors,

(November 25, 2014), at 20-33; Comments of Campaign for Tobacco-Free Kids and Tobacco Control Legal Consortium in Docket No. FDA-2014-N-1051, Reopening of Comments Period for Modified Risk Tobacco Product Applications: Applications for 10 Products Submitted by Swedish Match North America, Inc. (August 25, 2015); Comments of Campaign for Tobacco-Free Kids in Docket No. FDA-2018-N-2066, TPSAC Notice of Meeting re R.J. Reynolds Modified Risk Application for Camel Snus (August 29, 2018), at 6-9.

⁶⁶ FDA, Technical Project Lead Review for PMI heated tobacco products, April 29, 2019, at 83.

⁶⁷ Id.

regulatory systems, etc. that could make invalid any prediction of the likelihood of youth uptake in the U.S. based on the experience in these other nations.⁶⁸ FDA granted the IQOS PMTA in reliance on the Japanese and Italian data. FDA should not make a similar mistake, rendering any such decision subject to judicial challenge, by relying on the Swedish experience with snus in assessing the likely population-wide impact of the marketing of General snus as a modified risk product.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

⁶⁸ Id.