TO: The Honorable Lorena Gonzalez, Chair
Assembly Appropriations Committee
Members, Assembly Appropriations Committee

FROM: Norwood Associates, LLC

DATE: August 7, 2020

RE: SB 793 (Hill)—OPPOSE UNLESS AMENDED

NORWOOD ASSOCIATES
Government Relations

On behalf of our client, **Swedish Match North America (Swedish Match)**, we are writing to respectfully request your "**NO**" vote on SB 793, unless the bill is amended to exempt products discussed below that have obtained certain safety designations by the FDA and maintain a low youth usage rate.

SB 793 would prohibit tobacco retailers in California from selling any flavored tobacco product. However, recent amendments have exempted Hookah, premium cigars and pipe tobacco from the bill in recognition of the fact that the target of this legislation is primarily vape products and menthol cigarettes.

The real winners of this bill are cigarettes, while lower risk alternatives not used by teenagers will be removed from the market

While well intentioned, this bill would result in the banning of products, such as smokeless tobacco products and flavored non-tobacco nicotine products or "alternative nicotine products," such as our newest product ZYN, that consumers report help them stop using cigarettes. As such, consumers will have no option but to return to the most harmful product -- cigarettes. This is not good public policy, especially in light of concerns relative to increased risk and co-morbidity in COVID 19 cases for smokers. It is important now more than ever to rein in respiratory illnesses of all sorts given the budget deficit, economic challenges COVID-19 will continue to present, and Medi-Cal funding issues given that smokers are found to be disproportionately poor.

Moreover, smokeless tobacco products are significantly less likely to be used by youth. According to the California Department of Public Health's California Tobacco Fact and Figures 2019 only .8% of California teens have tried smokeless tobacco, even one time in a period of 30 days.[i] These products, and their primarily mint and wintergreen flavors, are simply not attractive to youth and therefore should not be included in this bill.

Lost Revenue during a time of budget deficit

As indicated above, youth usage of all smokeless tobacco products is a mere .8%. Furthermore, banning the sale of flavored smokeless tobacco products results in lost important revenue from products that are being utilized by legal consumers 21 years of age

and older, not youth. With California's large budget deficit, the state can ill afford to lose such revenue.

While the numbers anticipated in SB 739's fiscal analysis from Senate Appropriations are substantial, we believe those numbers are extremely understated. According to a California Department of Tax and Fee Administration Freedom of Information Act request made by Swedish Match and the assumptions made in the fiscal note from the 2019 Senate Bill 38 (Hill), the total estimated first year tax revenue loss by banning sales of flavored cigarettes and other tobacco products would approach $600,000,000. SB 38 is nearly identical to SB 793, with exception of the Hookah, cigar and pipe tobacco exemption.

Proposed Amendment

We have provided amendment language to the author and proponents this of this bill that would not only exempt certain smokeless products from the bill but, in addition, subject these products to an automatic future ban if the consequences of this exemption are that teenagers turn to these products as a result of the ban on flavored tobacco products. More specifically, Swedish Match has requested an amendment which would exempt our eight smokeless tobacco products that currently have a PMTA and MRTP designation from FDA from the bill, as well as smokeless nicotine only products (such as our product ZYN), so long as they maintain a youth usage rate of under 3% as determined by the California Department of Public Health.

The language proposed is as follows:

"(d) *"tobacco product" does not include any smokeless tobacco product that is subject to a current Premarket Tobacco Application and a Modified Risk Tobacco Product order by the United States Food and Drug Administration as of July 1, 2020 nor a smokeless nicotine product that is in the form of a solid, gel, gum or paste that does not contain tobacco and is intended for human consumption by means other than inhalation so long as the smokeless tobacco products and smokeless nicotine products maintain a youth usage rate of under 3%, as determined by the California Department of Public Health California Tobacco Facts and Figures 2019 or later years. "*

We would also point out that, according to the recent California Department of Public Health numbers, cigars have a youth usage rate of **.7%** and they were provided an exemption in the Assembly Health Committee while our products were not. The products covered under this this proposed exemption have a youth usage of **.8%.** Hookah has a youth usage rate of **1.8**%, even more alarming. Neither cigars, pipe tobacco or Hookah have designations from the FDA showing modified risk, while our eight smokeless products do and we have applied for a PMTA for our nicotine only product ZYN. Moreover, none of the other exemptions in the bill would automatically sunset if youth usage increases to just 3% as a result of the ban on flavored tobacco products, as we have proposed in our amendment.

BACKGROUND

Swedish Match is the only tobacco company with products that were granted both a PMTA and a MRTP by the FDA

To protect the public and create a healthier future for all Americans, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), signed into law on June 22, 2009, gives the United States Food and Drug Administration (FDA) authority to regulate the manufacture, distribution, and marketing of tobacco products.

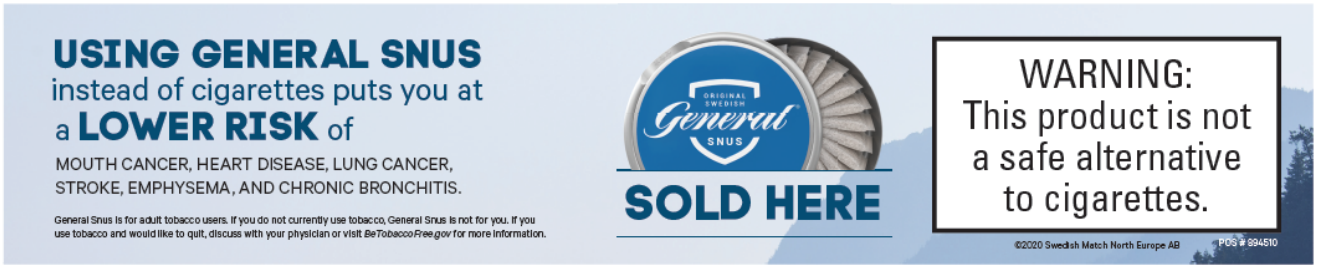
With this authority, the FDA granted eight Swedish Match snus smokeless tobacco products a premarket tobacco application (PMTA) in 2015 under the Obama administration. A PMTA is an application that must be reviewed and approved by the FDA before a new tobacco product can be legally marketed in the United States. There are several hurdles to overcome in achieving a PMTA certification. Of the 432 PMTAs filed, 375 were either "refused to accept" or the applicant, "refused to file" because the applicant withdrew. 86% of those submitted never made it to the review stage.

Through the pre-market review process, the FDA conducts a science-based evaluation to determine whether a tobacco product meets the applicable statutory standard for marketing authorization—for example, whether the product is appropriate for the protection of public health with respect to the risks and benefits of the product to the population as a whole, including tobacco product users as well as non-users, and taking into account, among other things, the likelihood that those who do not use tobacco products will start using them and the product must be shown to be of interest to cigarette smokers as they are looking for products to use instead of cigarettes. In short, the FDA is determining that this product is lower risk for consumers than other products on the market.

The Office of Science, in assessing the FDA order, stated:

> "The proposed products are reported to have flavors such as mint, wintergreen, or tobacco character with citrus. These proposed flavors are consistent with traditionally available [smokeless tobacco] flavors and **are not novel flavors that likely increase appeal to youth.[**1] Additionally, in that ruling the FDA stated that the smokeless tobacco product called snus is low risk. FDA assessed the risk posed to the individual as well as the population as a whole, and judged that the products met the standard in the 2009 US Tobacco Control Act. FDA also considered the fact that the products come in mint and wintergreen flavors. It is significant that the Swedish Match snus products are currently determined by FDA to be **"appropriate to the protection of the public health", and that these products are flavored, and are smokeless."**

Furthermore, on October 22, 2019, the FDA granted the **first-ever** modified risk designation (MRTP) to Swedish Match for eight snus smokeless tobacco products. This means the FDA considers it appropriate and beneficial to public health that the eight products be advertised specifically **as harm-reducing**, with specific information about the diminished risks of certain health conditions arising where Swedish Match products are used instead of smoking cigarettes or instead of other like products. Below is an example of one of our new advertisements under the MRTP designation:



To market a product as a modified risk tobacco product (MRTP), tobacco companies must now first demonstrate to FDA that a proposed MRTP will, or is expected to, benefit the health of the U.S. population as a whole – including adults and children, tobacco users and nonusers. Further, to fulfill the requirements of the MRTP and address concerns about youth usage, Swedish Match submitted extensive scientific evidence showing that non-users of tobacco, including young adults, did not intend to buy any of the eight products. The modified risk claim did not make them more likely to buy the products. Please note, two of the eight approved products are mint flavored and one wintergreen.

Senator Hill has repeatedly said Swedish Match should apply to the FDA to get their tobacco product authorized as a cessation device. Swedish Match has already spent numerous years, countless resources and millions of dollars to obtain the PMTA and MRTP designations from the FDA stating their products are the lower risk and can be advertised as such. To apply for a cessation designation could take another 3 to 5 years, and in the meantime these lower risk alternatives would be off the market and not available to consumers should SB 793 be signed into law. Moreover, consumer data has indicated that our customers like the fact that our products are not considered cessation devices and are accessible at the same locations they can purchase tobacco products. Quitting smoking is as much a mental struggle as it is physical and using products such as snus or ZYN that they can purchase at a convenience store like a tobacco product and not a pharmaceutical one helps with the mental aspect of quitting one product (cigarettes) and replacing it with another lower risk alternative.

ZYN vs. Nicorette

Our newest and most innovative product, ZYN, is a nicotine only product. ZYN is made with pharmaceutical-grade nicotine salt, along with other natural and artificial ingredients for a nicotine experience that is 100% tobacco free. This alternative nicotine product contains the same ingredients as Nicorette and is offered in many of the same flavors. However, under the bill, ZYN would be banned while Nicorette would not. Ironically, Nicorette is easier for youth to obtain and does not contain some of the safety and child prevention measures such as childproof packaging that ZYN products incorporate. ZYN provides consumers with yet another option for quitting smoking. Cessation methods such as Chantix and the patch are not right for everyone. The patch can be too much for those smokers not smoking a pack a day. ZYN allows consumers to choose how much works for them and at what level with two different milligram options. Furthermore, ZYN is more affordable than Nicorette. Moreover, it feels and acts like a typical tobacco product but is 100% tobacco free. It is for these reasons and others that consumers have been contacting Swedish Match to share stories of their successes with quitting cigarettes using ZYN during this frightening time of COVID.

For all of the above reasons, we urge your **"NO"** vote of AB 793 unless it is amended as proposed above. As always, we are available at your convenience to further discuss these amendments or respond to any questions you may have relative to this issue.

Thank you.

cc: Jano Dekermenjian, Office of Senator Hill
Lisa Murawski, Principal Consultant, Assembly Appropriations Committee
Joe Shinstock, Consultant, Assembly Republican Caucus

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[i] *Vuong TD, Zhang X, Roeseler A. California Tobacco Facts and Figures 2019. Sacramento, CA: California Department of Public Health; May 2019.*