CAPITOL OFFICE
STATE CAPITOL
SACRAMENTO, CA 95814
TEL (916) 651-4013
FAX (916) 651-4913

DISTRICT OFFICE
1528 S. EL CAMINO REAL
SUITE 303
SAN MATEO, CA 94402
TEL (650) 212-3313
FAX (650) 212-3320

SENATE.CA.GOV/HILL
SENATOR.HILL@SENATE.CA.GOV

California State Senate

SENATOR
JERRY HILL
THIRTEENTH SENATE DISTRICT

COMMITTEES
LABOR, PUBLIC EMPLOYMENT & RETIREMENT
CHAIR
APPROPRIATIONS
BUSINESS, PROFESSIONS & ECONOMIC DEVELOPMENT
ENERGY, UTILITIES & COMMUNICATIONS
ENVIRONMENTAL QUALITY
GOVERNMENTAL ORGANIZATION

August 17, 2020

Mr. Mitchell Zeller
Director, Center for Tobacco Products
U.S. FOOD AND DRUG ADMINISTRATION Building 71, Room G335
10903 New Hampshire
Avenue Silver Spring, MD
20993-0002

Transmitted via email to: Mitchell.Zeller@fda.hhs.gov

RE: Swedish Match's product representations in its campaign against proposed state legislation restricting the sale of flavored tobacco products

Dear Mr. Zeller:

We write to call your attention to statements made on behalf of Swedish Match regarding its snus and ZYN products in an effort to secure amendments to SB 793, a bill being considered by the California Legislature to restrict the sale of flavored tobacco products in the State of California. These communications conflict with provisions of the Family Smoking Prevention and Tobacco Control Act that prohibit the promotion of tobacco products for cessation or therapeutic purposes, with modified risk claims without FDA authorization, or with representations that they are "approved" by FDA.

Specifically, on August 7, 2020, Norwood Associates "on behalf of [its] client, Swedish Match North America (Swedish Match)" wrote Assemblywoman Lorena Gonzalez, Chair of the California Assembly Appropriations Committee, as well as all members of the Appropriations Committee, urging that SB 793 be amended to exempt smokeless tobacco products from the bill.

1. Illegal cessation claims

The Norwood Associates letter makes several statements on behalf of Swedish Match that are directly or thinly veiled cessation claims. Because Swedish Match has neither sought nor obtained approval under FDA's drug/device authorities to promote or market Swedish

Match snus or ZYN for **cessation**, the following claims are illegal (**bold** and *italics* added for emphasis).

- 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.*** [page 1]

- Quitting smoking is as much a mental struggle as it is physical and ***using products such as snus or ZYN…helps with the mental aspect of quitting*** one product (cigarettes) and replacing it with another lower risk alternative. [page 4]

- ZYN provides consumers with yet ***another option for quitting smoking***. [page 5]

- … consumers have been contacting Swedish Match to share stories of their ***successes with quitting cigarettes using ZYN*** during this frightening time of COVID. [page 5]

Swedish Match's agent makes a direct comparison between ZYN and Nicorette, an FDA approved smoking cessation therapy:

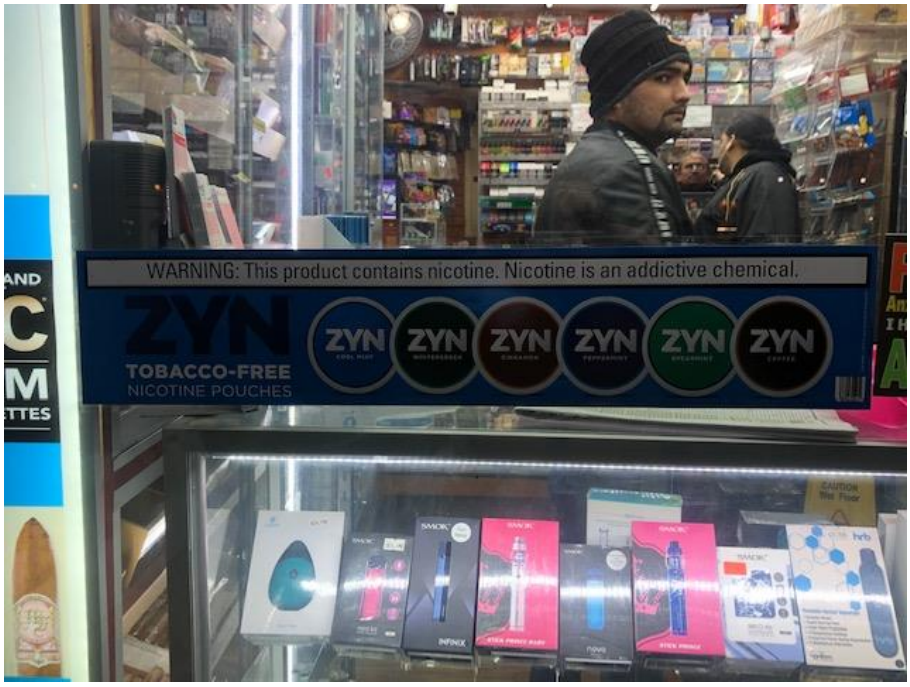
> **ZYN vs. Nicorette**
>
> Our newest and most innovative product, ZYN, is a nicotine only product. ZYN is made with pharmaceutical-grade nicotine salt, along with other natural and artificial ingredients for a nicotine experience that is 100% tobacco free. This alternative nicotine product contains 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.

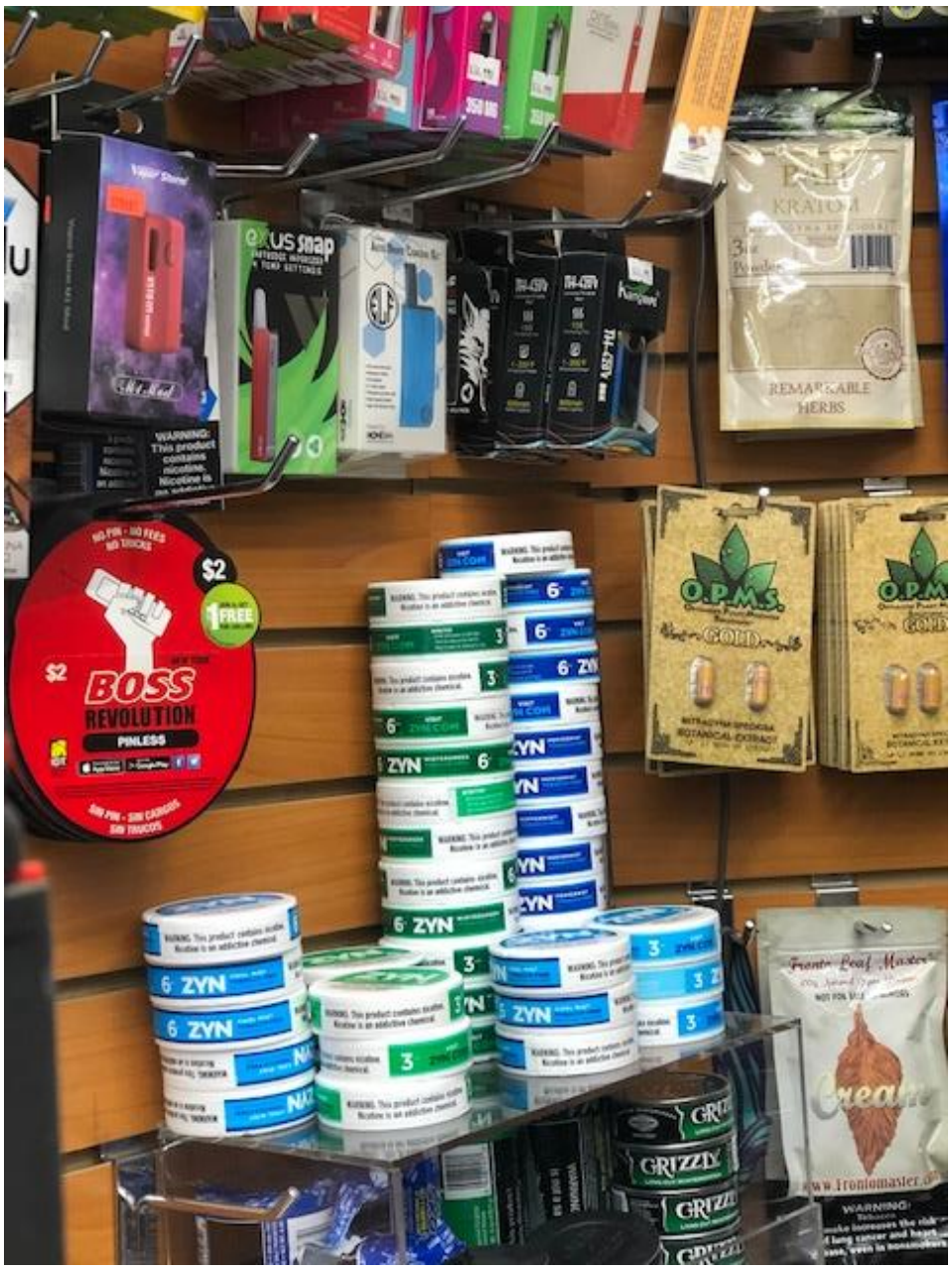
Comparing ZYN to Nicorette is tantamount to saying that ZYN is a cessation product. However, while Nicorette has undergone premarket review by FDA and has been approved for sale as a cessation aid, **Swedish Match has not sought or been granted approval to sell ZYN for cessation.**

2. Illegal modified risk claims

Norwood Associates' claims made on behalf of Swedish Match that ZYN is "tobacco free" and uses "pharmaceutical-grade nicotine salt" are implicit, if not explicit, modified risk tobacco product (MRTP claims. And since Swedish Match has not obtained FDA authorization to promote or market ZYN with MRTP claims, they are illegal. The phrase "tobacco free" is misleading. Even if ZYN does not contain tobacco leaf (which is itself an unsubstantiated claim since ZYN has not undergone Premarket Tobacco Product Application [PMTA] review), ZYN contains nicotine, which is tobacco derived, and is therefore a "tobacco product" under both California and federal law. Use of the term "pharmaceutical-grade" is also both unsubstantiated and misleading, since it suggests that these ingredients were somehow approved by FDA's drug authorities and are safer than those found in other tobacco products.

These claims also feature prominently in Swedish Match's marketing of ZYN, as illustrated by these examples of point-of purchase marketing:





3. Illegal representations that Swedish Match products are "approved" by FDA

FDA's November 10, 2015 marketing order for Swedish Match snus contains the following language:

> This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C At. This marketing order is subject to withdrawal or

temporary suspension under section 910(d) of the FD&C Act.

FDA's October 22, 2019 MRTP orders for Swedish Match snus contains nearly identical language:

> These orders authorizing the marketing of these modified risk tobacco products do not mean FDA "approved" the modified risk tobacco products specified in Appendix A; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads, or would mislead consumers into believing, among other things, that the modified risk tobacco products specified in Appendix A are "approved" by FDA. The modified risk tobacco products subject to these modification orders are subject to withdrawal as described in section 911(j).

Despite these clear exhortations, Swedish Match through its agent Norwood Associates made express statements and implied representations in its letter to consumers on the Assembly Appropriations Committee that Swedish Match snus smokeless tobacco products were "approved by the FDA" [page 3] and, "Please note, ***two of the eight approved products*** are mint flavored and one wintergreen." [page 4, emphasis added] These statements are in direct violation of both the PMTA and MRTP orders and would likely mislead the readers into believing that FDA approved Swedish Match snus as less harmful products.

Pursuant to the authorities cited in the above excerpts, FDA should withdraw both the PMTA marketing order and the MRTP orders. Until such actions can be taken, we urgently request that FDA immediately issue an order directing Swedish Match to instantly:

1) cease and desist making these illegal cessation claims about ZYN and Swedish Match Snus;
2) cease and desist making unauthorized MRTP claims about ZYN; and
3) cease and desist from making express or implied representations that Swedish Match snus was "approved" by FDA.

Sincerely yours,

Jerry Hill
Senator, 13th District

Jim Wood
Assemblymember, 2nd District

Kevin McCarty
Assemblymember, 7th District

CC:

Mr. Anthony Villa,
Senior Regulatory Counsel, Office of Compliance and
Enforcement FDA Center for Tobacco Products
Anthony.Villa@fda.hhs.gov

Ms. Ann Simoneau, J.D.
Director, Office of Compliance and
Enforcement FDA Center for Tobacco
Products Ann.Simoneau@fda.hhs.gov

Dr. Janet Woodcock
Director, FDA Center for Drug Evaluation and Research

Mr. Donald Ashley
Director of Compliance, FDA Center for Drug Evaluation and Research

Hon. Jackie Speier
Member, U.S. House of Representatives

Hon. Nancy Pelosi
Speaker of the House,
U.S. House of Representatives

Hon. Raja Krishnamoorthi
U.S. House of Representatives,
Chairman, Oversight Subcommittee on Economic and Consumer Policy