



January 22, 2019

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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

Dear FDA Dockets Management Staff:

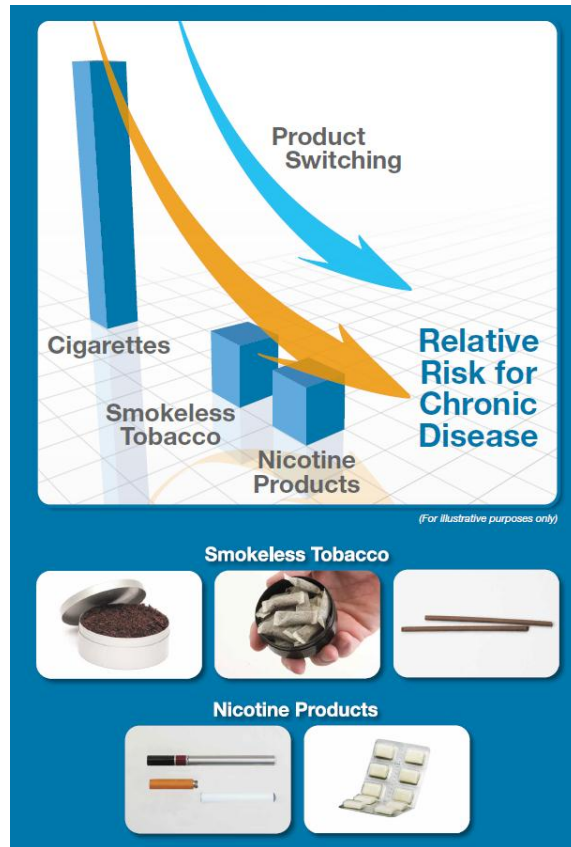
The National Association of Tobacco Outlets, Inc. (NATO) respectfully submits these comments in support of the eight Modified Risk Tobacco Product Applications (MRTPs) originally submitted by Swedish Match North America, Inc. (Swedish Match) on June 10, 2014 and subsequently amended in response to recommendations from the Center for Tobacco Products (CTP). Swedish Match filed MRTPs for the following snus smokeless tobacco products: General Loose, General Dry Mint Portion Original Mini, General Portion Original Large, General Classic Blend Portion White Large (12 count), General Mint Portion White Large, General Nordic Mint Portion White Large (12 count), General Portion White Large, and General Wintergreen Portion White Large.

NATO is a national trade association that represents more than 60,000 retail stores across the country. The association keeps its members abreast of tobacco-related rules and regulations on the local, state and federal level in order to maintain a high level of compliance. We communicate and work with all levels of government, including the FDA, to ensure that products are sold to only to adults, consistent with the applicable laws in each jurisdiction.

The Continuum of Risk and General Snus Products

On July 28, 2017, FDA Commissioner Scott Gottlieb announced a new comprehensive regulatory plan that focused on nicotine and the delivery of nicotine through various products as measured on a “continuum of risk.” It is widely accepted in both the public health and scientific communities that a continuum of risk philosophy, coupled with a harm reduction strategy, is in the best interest of the public health and those consumers that use tobacco products.

This continuum of risk places combustible tobacco products on the higher end of the spectrum as being the most harmful while nicotine replacement therapies are on the opposite end of the spectrum as the most beneficial for tobacco consumers. In between these two extremes is a range of measurable harm with smokeless tobacco products falling nearer to nicotine replacement therapies on the lower end of the spectrum. The continuum of risk concept shows in the graphic below that not all tobacco products are equal in terms of harm and smokeless tobacco products fall on less harmful end of the spectrum.



Harm Reduction Statements in the Swedish Match MRTPs

Under the provisions of the Family Smoking Prevention and Tobacco Control Act, the MRTTP application process is a key pathway to inform consumers about the relative risk of various tobacco products, with an emphasis on reduced risk products. In fact, one of the primary criteria for the FDA to approve a MRTTP application statement is whether the claim is appropriate for the protection of the public health.

FDA regulations enacted pursuant to the Family Smoking Prevention and Tobacco Control Act prohibit companies themselves from making product health claims, except through the modified risk orders issued by FDA through the MRTTP process. Approval of the modified risk orders for these Swedish Match smokeless tobacco snus products would provide critically important and scientifically sound information to adult consumers that will allow them to make informed decisions affecting their health.

First, NATO acknowledges the CTP decision to not reject outright the specific claims requested by Swedish Match in its initial MRTTPs, but instead offer specific, written recommendations and suggestions to correct deficiencies it found in the application, and providing specific recommendations in response to those applications. In its letter to Swedish Match, CTP specifically indicated that “changing the proposed claims, supplementing the evidence, and conducting new studies could provide sufficient evidence to issue the relevant modified risk orders in the application.”

Next, NATO also acknowledges that Swedish Match has worked constructively with regulators to address specific issues and amend its initial applications. The actions of both the CTP and Swedish Match serve the interests of adult tobacco consumers and the public health. We strongly encourage CTP to issue the requested modified risk orders so that adult consumers, many of whom shop at our member stores, can have access to accurate information to make informed decisions.

It is also important to note that in its amended MRTPs, Swedish Match has indicated its willingness to retain a label statement as requested by the CTP which reads: “WARNING: This product is not a safe alternative to cigarettes.” Additionally, Swedish Match has developed three modified risk claims based upon statements made by CTP and by qualitative research performed by the company. The claims are as follows:

Claim 1: “Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

Claim 2: “Using General Snus instead of cigarettes would significantly reduce harm and the risk of certain tobacco-related diseases to individual tobacco users.”

Claim 3: “No tobacco is totally safe, but using General Snus instead of cigarettes puts you at a lower risk of chronic lung disease and other tobacco-related ailments.”

Each of these claims is clearly supported by a review of the scientific literature provided by Swedish Match to the FDA and it NATO’s understanding that Swedish Match is only pursuing Claim 1 in its MRTP applications. The benefits of switching to snus non-combustible delivery should be communicated to the public, as approval of these MRTP applications would allow.

It is also worth noting that smoking rates in many European countries are extraordinarily high, even higher than in the United States. One notable exception to the high smoking rates is Sweden where the adult smoking rate is 5% and for decades consumers have either switched to snus products or initiated and maintained use of snus, never migrating to smoking. It follows that smoking-related disease and mortality in Sweden is also much lower than other countries.

It is critically important that Swedish Match be afforded the opportunity to responsibly share this important information with its adult consumers. Many of these consumers shop at the 60,000+ retail locations represented by our association. Our members’ adult customers should be provided this information so they can make informed decisions on the tobacco products they purchase.

Perhaps most importantly, the American public deserves access to accurate, scientifically valid information upon which to make informed health decisions. The only mechanism that legally provides for this final option is for FDA to approve the Swedish Match MRTPs and issue modified risk orders for the eight General Snus products requested.

NATO appreciates the opportunity to submit comments on behalf of its retail members and in support of the Swedish Match modified risk tobacco product applications. We urge the FDA to act favorably on the Swedish Match MRTP submissions.

Sincerely,

Thomas Briant

NATO Executive Director and Legal Counsel