NATO

January 22, 2019

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

RE: Docket No. FDA-2018-N-3261-0001, Modified Risk Tobacco Product Application: Application for Copenhagen Snuff Fine Cut, a Loose Moist Snuff Tobacco Product Submitted by U.S. Smokeless Tobacco Company LLC

Dear FDA Dockets Management Staff:

The National Association of Tobacco Outlets, Inc. (NATO) submits these comments in support of the modified risk tobacco product application (MRTP) for Copenhagen Snuff Fine Cut submitted by U.S. Smokeless Tobacco Company LLC (UST). This application for a reduced harm statement should be approved by the U.S. Food and Drug Administration (FDA) because the public needs to be informed of factual information about Copenhagen Snuff Fine Cut moist snuff as a less harmful alternative tobacco product.

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.

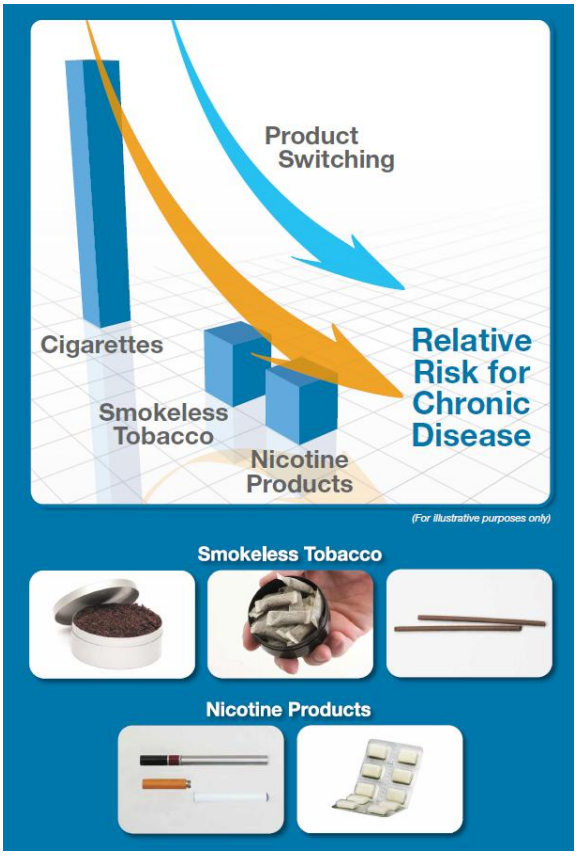
This letter will focus on two key points. First, Copenhagen Snuff Fine Cut conforms to the FDA's stated goal of protecting the public health because the product falls on the lower end of the FDA-embraced "continuum of risk" spectrum and represents a less harmful product compared to combustible tobacco products. Second, the approval of the MRTP application will provide retailers the opportunity to inform consumers about the lower health risk of Copenhagen Snuff Fine Cut to help realize the harm reduction opportunity that moist snuff tobacco products present.

The Continuum of Risk and Copenhagen Snuff Fine Cut

On July 28, 2018, 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 measureable 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.



Under the provisions of the Family Smoking Prevention and Tobacco Control Act, the MRTP 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 MRTP application statement is whether the claim is appropriate for the protection of the public health. With regard to the MRTP application for Copenhagen Snuff Fine Cut, UST is seeking approval of the modified risk claim that reads: "If you smoke, consider this: Switching completely to this product from cigarettes reduces risk of lung cancer."

The scientific and evidentiary data submitted by UST to support the MRTP application and the modified risk claim for Copenhagen Snuff Fine Cut is extensive and will not be repeated in these comments. At the same time, it is important to underscore the fact that U.S. government data from

the National Health Interview Survey (NHIS) and the National Longitudinal Mortality Study (NLMS) confirm that moist smokeless tobacco products are far lower in health risk compared to conventional cigarettes.

A decision by the FDA approving the MRTP application for Copenhagen Snuff Fine Cut would allow consumers to be informed of the lower risk propensity of the product and support the overall goal of the agency to help adults who still need or want nicotine to obtain it from less harmful products.

Retailers Can Be a Source of Accurate Risk Information on Copenhagen Snuff Fine Cut

One of the most common places for adult consumers to receive information about tobacco products is at their local retail store. Adult tobacco consumers regularly patronize our member stores which provides the opportunity for them to be informed about the relative health risks of tobacco products sold in the store. This health risk information can be in the form of point of sale displays, interaction with retail store employees about tobacco products, and labeling on tobacco products.

If the FDA were to issue a favorable decision approving the MRTP application for Copenhagen Snuff Fine Cut smokeless tobacco, then retailers would be able to show the MRTP statement in point of sale displays or on product packaging and respond to customer inquiries about Copenhagen Snuff Fine Cut. That is, the retail segment of the industry can serve as a source of accurate information about the relative health risk of Copenhagen Snuff Fine Cut as approved by the FDA.

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 U.S. Smokeless Tobacco Company MRTP and issue a modified risk order for Copenhagen Snuff Fine Cut.

NATO appreciates the opportunity to submit comments on behalf of its retail members and in support of the Copenhagen Snuff Fine Cut modified risk tobacco product application. We urge the FDA to act favorably on the MRTP submission.

Sincerely,

Thomas A. Briant

NATO Executive Director and Legal Counsel