EXHIBIT I

FDA NEWS RELEASE

FDA grants first-ever modified risk orders to eight smokeless tobacco products

FDA concludes completely switching from cigarettes to these authorized products lowers certain health risks

For Immediate Release:

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The U.S. Food and Drug Administration announced today that, for the first time, it has authorized the marketing of products through the modified risk tobacco product (MRTP) pathway. The authorizations are for eight Swedish Match USA, Inc. snus smokeless tobacco products sold under the "General" brand name.

These products had previously been authorized for U.S. sale without modified risk claims by the FDA in 2015 in response to filings of premarket tobacco applications (PMTAs). Today's action further authorizes the manufacturer to market these specific products with the claim "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 FDA made this authorization after reviewing scientific evidence submitted by the company that supports this claim. In an effort to help prevent youth access and exposure, the agency has also placed stringent advertising and promotion restrictions on the products, including a requirement to restrict advertising to adults. In addition, the products' packaging and advertising must also bear the warning statements (/tobacco-products/labeling-and-warning-statements-tobacco-products/smokeless-tobacco-labeling-and-warning-statement-requirements) required for all smokeless tobacco products.

While today's decision permits the eight General brand snus smokeless tobacco products to be sold in the U.S. with a modified risk claim, it does not mean these products are safe or "FDA approved." All tobacco products are potentially harmful and addictive, and those who do not use tobacco products should continue to refrain from their use. The modified risk orders are product-specific and limited to five years.

"Today's action demonstrates the viability of the pathway for companies to market specific tobacco products as less harmful to consumers, but only following a thorough scientific evaluation by the FDA. Our team of scientific experts examined these applications to ensure that the tobacco products meet the public health standards in the law. While we are authorizing these specific modified risk tobacco products, it's important for the public to understand that all tobacco products — including these — pose risk. Anyone who does not currently use tobacco products, especially youth, should refrain from doing so," said Acting FDA Commissioner Ned Sharpless, M.D. "In addition to stringent restrictions to limit youth access and exposure to advertising, this time-limited authorization comes with a number of postmarket requirements that will allow us to keep a close watch on the marketplace. Should any information lead us to determine that the marketing of these products as posing less risk no longer benefits the health of the population as a whole, the agency would consider withdrawing this authorization."

While all tobacco products pose risks, the MRTP pathway outlined in the 2009 Family Smoking Prevention and Tobacco Control Act allows companies to submit applications for the FDA to evaluate whether a tobacco product may be sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. In its review, the FDA generally must look at whether the applicant

has demonstrated that the product – as actually used by consumers – will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole. This includes taking into account both users of tobacco products and persons who do not currently use tobacco products. In making this assessment, the agency must consider, among other things, whether those who do not use tobacco products would start using the product and whether existing tobacco users who would have otherwise quit would switch to the modified risk product instead. Today's announcement marks the first time that the FDA has authorized an MRTP.

The FDA's review determined that the claim proposed by the company in its application is supported by scientific evidence, that consumers understand the claim and appropriately perceive the relative risk of these products compared to cigarettes, and that the modified risk products, as actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole.

In particular, the available scientific evidence, including long-term epidemiological studies, shows that relative to cigarette smoking, exclusive use of these specific smokeless tobacco products poses lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis. Evidence submitted in the application also demonstrated that consumers can understand the claim and the relative risk of the products, and that seeing the claim influenced their intentions to buy the products among smokers 25 years of age or older – a group who stands to benefit the most from the modified risk tobacco products. Consumers also generally understood that the risk reduction is not achieved from partial switching (i.e., dual use of the products with continued use of cigarettes), thereby increasing the likelihood that smokers will switch completely. In addition to these lower risks relative to cigarette smoking, the FDA previously determined that the levels of two potent carcinogens in smokeless tobacco products called NNN and NNK (/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list) are lower in these General snus products than the vast majority of smokeless tobacco products on the U.S. market. In addition, the evidence showed when used exclusively instead of other smokeless tobacco products, the General snus products offer the potential for reductions in oral cancer risk.

The available evidence does not demonstrate significant youth initiation of these products, and evidence submitted by the company also found low levels of intentions to buy the product among non-users of tobacco (including young adults) and, importantly, found that the inclusion of the modified risk claim did not affect these intentions. In addition, to further limit the likelihood of youth initiation, the FDA is placing stringent restrictions on how the products are advertised and promoted – particularly via websites and through social media platforms – by including restrictions that prevent advertising from being targeted to youth.

With the authorization of these products, the company is required to conduct postmarket studies to determine the impact of modified risk tobacco product orders on consumer perception, behavior, and health. Relatedly, the FDA will evaluate new available data regarding the products through postmarket records and reports required in the modified risk orders. The company is required to report regularly to the FDA with information regarding the products on the market, including, but not limited to, ongoing and completed consumer research studies, advertising, marketing plans, sales data, information on current and new users, manufacturing changes and adverse experiences.

To continuously market these same products with the same modified risk information beyond the five-year limit would require the company to submit a request for renewal and receive renewal authorization from the FDA before the current orders expire. The FDA may withdraw the initial and any potential subsequent modified risk

orders if the agency determines that, among other things, the continued marketing of the product no longer benefits the health of the population as a whole.

Prior to today's MRTP authorization, the eight General brand snus smokeless tobacco products were authorized to be marketed (http://wayback.archive-it.org/7993/20180125101455/https:/www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm472026.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) without modified risk claims through the PMTA pathway in November 2015.The FDA's review of those applications found, among other things, that levels of harmful and potentially harmful constituents in these products are lower than most other smokeless tobacco products. The FDA previously denied (http://wayback.archive-it.org/7993/20180125072029/https:/www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm533219.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) an MRTP request from the company for these same products to remove a currently required warning stating that the products can cause gum disease and tooth loss. At that time, the FDA also issued a response to the applicant's requests to remove a currently required warning stating that the products can cause mouth cancer and to revise a currently required warning stating that the products are not a safe alternative to cigarettes. This response offered the company an option to amend its MRTP applications.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- Modified Risk Tobacco Products (/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products)
- Modified Risk Orders (/tobacco-products/advertising-and-promotion/modified-risk-orders)

- Swedish Match USA, Inc. MRTP Applications (/tobacco-products/advertising-and-promotion/swedish-match-usa-inc-mrtp-applications)

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