United States Senate
WASHINGTON, DC 20510

April 16, 2015

Mitch Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Director Zeller:

We urge you to reject Swedish Match Tobacco Company's application to market ten of its "snus" products as "modified risk tobacco products." Snus, a kind of powdered tobacco derived from snuff, has been found to increase the risk of several serious health problems. Swedish Match currently markets several snus products in the United States with the same warning labels required for all smokeless tobacco products. Its application, which seeks to modify these labels, is both legally defective and factually unjustified, and the Food and Drug Administration (FDA) should accordingly reject it.

Under current law, all smokeless tobacco products, including snus, are required to bear one of the following warning labels.

WARNING: This product can cause mouth cancer.
WARNING: This product can cause gum disease and tooth loss
WARNING: This product is not a safe alternative to cigarettes
WARNING: Smokeless tobacco is addictive.

Swedish Match's application seeks permission for its snus products to bear only the fourth label or a modified version of the third, which would read, "*No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.*"

First, Swedish Match seeks to make improper use of the "modified risk" application process. This process, established under the Family Smoking Prevention and Tobacco Control Act of 2009, allows companies to apply to FDA for permission to claim – on a product's packaging, in advertisements, or elsewhere – that a specific tobacco product is less harmful than other tobacco products. Whether the company may make such a claim is a separate issue from whether the product must include a government-mandated warning label.

In other words, a successful modified risk application could allow a company to include the claim on a package beside a warning label, but the granting of the application would not in itself permit the company to remove or modify the label. A company wishing to alter the warning-label requirement must use a separate application process. Swedish Match has not identified a specific, separate claim of modified risk that it wishes to make; instead, it seeks to

graft such a claim into an alteration of the warning-label requirement. The Tobacco Control Act does not permit this, and this in itself provides sufficient grounds to reject the application.

Second, even if Swedish Match had properly applied for permission to make the separate claim that snus products "present substantially lower risks to health than cigarettes," the evidence it has presented would not justify granting the request. The Tobacco Control Act requires a company to make a two-part showing: that a product "as it is actually used by consumers, will (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and (B) benefit the health of the population as a whole." The FDA must find that there will be a net benefit overall – taking into account the negative effects of any increase in the number of tobacco users or reduction in the number of users who quit, alongside the positive effects of reduced harm to individual users.

Swedish Match has not made the necessary showing. Smokeless tobacco products have too often been promoted by tobacco companies as a way to avoid quitting smoking. A misleading warning label could encourage former smokers to start using snus. Moreover, a reduced risk warning label could mislead non-tobacco users into believing that the health risks posed by these products are negligible and thus result in an increase in initiation by non-users, particularly young people. Swedish Match has not presented sufficient evidence to counter these possibilities.

Moreover, the changes that Swedish Match seeks to make to the warning labels are misleading in and of themselves. As you know, FDA's Tobacco Products Scientific Advisory Committee (TPSAC) met earlier this month to analyze Swedish Match's application and considered several specific scientific questions. Although TPSAC was split on some questions, the committee unanimously concluded that Swedish Match's proposed warning statement did not adequately communicate the potential health risks of snus products. TPSAC also found that more research was needed to justify ruling out certain health risks such as adverse effects on pregnancy, decreased risk of tooth loss, gum disease, or oral cancer. These conclusions echo troubling findings from other sources indicating that Swedish snus products increase the risk of fatal heart attacks and stillbirths and, according to some studies, may increase the risk of pancreatic and esophageal cancer.

We believe that even if Swedish Match had submitted a proper modified risk request, the paucity of evidence it has provided – and TPSAC's numerous concerns – would compel FDA to reject the application. We hope that you will do so now, and that you will remain attentive to these issues should future applications from Swedish Match or other smokeless tobacco companies come before you. We look forward to continuing to work with you on this issue, and we thank you for your attention.

Sincerely,

RICHARD BLUMENTHAL
United States Senate

RICHARD J. DURBIN
United States Senate

SHERROD BROWN
United States Senate

BARBARA BOXER
United States Senate

JEFF MERKLEY
United States Senate

JACK REED
United States Senate