Dr. Scott Gottlieb  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  


August 28, 2018  

Dear Commissioner Gottlieb:

The U.S. Food and Drug Administration (FDA) recently issued a “public comment of modified risk tobacco product applications (MRTPAs) for six Camel Snus smokeless tobacco products submitted by R.J. Reynolds Tobacco Company.”

Experts at The Heartland Institute, a nonpartisan think tank, have researched the effects of smokeless tobacco and tobacco harm reduction products for more than 20 years. According to our research, the smoke in combustible cigarettes poses the biggest threat to smokers. Therefore, smokeless tobacco can deliver nicotine more safely. Evidence indicates snus products, including Camel Snus, deliver nicotine effectively without the associated harms of combustible cigarettes.

FDA recognizes a continuum of risk among tobacco products: Combustible cigarettes are the most harmful and smokeless tobacco and snus are less harmful. However, despite this acknowledgement, FDA regulations prevent snus manufacturers from marketing their products as less harmful than combustible cigarettes. In fact, the warnings required on snus products misinform the public.

Therefore, The Heartland Institute urges FDA to regulate Camel Snus products and combustible cigarettes differently. Because FDA has recognized and accepted the continuum of harm posed by different tobacco products, FDA should approve the modified risk tobacco product application. Approving the application would clarify the health effects of different tobacco products and hopefully incentivize smokers to quit using combustible cigarettes.

Tobacco Harm Reduction

Of the 39 million adult smokers in the United States, approximately 480,000 die each year from smoking-related illnesses. Over the next 20 years, an estimated 9.6 million Americans will die because of tobacco-related diseases. Despite a landmark study in 1964 that linked combustible tobacco use to increased cancer risk, many efforts to reduce smoking have failed. Tobacco control efforts, including
regulations, sin taxes, and public education campaigns, intended to reduce cigarette smoking have failed to significantly impact smoking consumption.

These efforts have failed because the “quit or die” strategy does not resonate with all smokers. Under this strategic campaign, smokers are typically limited to two cessation choices: behavioral therapy or “the use of pharmaceutical nicotine and other medications.” However, there is another approach: tobacco harm reduction (THR) products. THR includes tobacco or nicotine in products designed to reduce the harms associated with traditional tobacco products, such as combustible cigarettes.

Research shows it is the smoke created by the burning of tobacco, rather than the nicotine, that produces the harmful constituents found in combustible cigarettes. THR products—including smokeless tobacco, snus, electronic cigarettes and vaping devices, and heat-not-burn products—are already on the market in the United States. All these products effectively deliver nicotine without the risks associated with the burning of tobacco.

It is important for regulatory agencies to understand that nicotine, while addictive, is relatively harmless when consumed outside of combustible cigarettes. The Schroeder Institute for Tobacco Research and Policy Studies concluded “nicotine itself, while not completely benign, carries substantially lower risks than smoking.”

In a comprehensive study on nicotine health effects, Raymond Niarua, Ph.D., noted “that even very high doses of medicinal nicotine had little effect on cardiovascular function.” Emphasizing “a continuum of harm among combustible and noncombustible, nicotine-containing products,” Niarua urged the use of alternative nicotine products, with “the goal of moving users away from the most addictive, appealing and toxic combustible to less harmful alternatives—ideally FDA-approved [modified risk tobacco products].” The U.S. surgeon general and the Royal College of Physicians agree that “nicotine, while addictive, is not the primary cause of smoking-related diseases.”

Smokeless Tobacco and Snus

Humans have used smokeless tobacco products for centuries, and these products were “the dominant form of tobacco used in the U.S. until the early 20th century.” Today, the most popular forms of tobacco include moist snuff, chewing tobacco, and American and Swedish snus.

Camel Snus is very similar to Swedish snus, and data from Sweden and other countries provide significant evidence that snus poses considerably fewer risks than combustible cigarettes. Dr. Brad Rodu, a senior fellow at The Heartland Institute, has conducted more than 20 years of research on the effects of smokeless tobacco.

In an analysis of Swedish tobacco consumption, Rodu found that although Swedish men have the highest rate of smokeless tobacco use in Europe, they have the lowest smoking rate. If nicotine were to cause cancer, “one would expect snus use to be associated with increased risk of lung cancer and many other cancers.” Consequently, “Swedish men also have the lowest rates of lung cancer and other smoking-related disease in Europe.” Rodu found that smokeless tobacco is “at least 98 percent safer even though most Americans are misinformed about the differences in risk.”
A summary of the “epidemiological evidence relating to snus and health” revealed snus usage is not associated with “cancer of the oropharynx, oesophagus, stomach, pancreas, lung or other sites, or with heart disease.” Another study found using snus is safer than smoking and that “any effects of snus on the risk of cancer or [circulatory disease], if they exist, are probably no more than 1% of that of smoking.”

R.J. Reynolds first introduced Camel Snus to “several major metropolitan areas” in 2006, offering three varieties: “Original,” “Frost,” and “Spice.” Camel Snus became available nationally in 2008. R.J. Reynolds has more than 10 years of data examining the potential risks associated with Camel Snus. Moreover, included in the modified risk tobacco application are a plethora of studies analyzing the chemistry, toxicity, carcinogenicity, and perception of Camel Snus. R.J. Reynolds’ evidence aligns with ample evidence that shows smokeless tobacco and snus products are less harmful than combustible cigarettes.

**Regulatory Processes Should Promote Evidence-Based Marketing Standards**

Despite more than 20 years of research indicating smokeless tobacco and snus have a reduced risk profile, many Americans are misinformed about nicotine’s true effects. A recent survey revealed a majority of American adults incorrectly believe nicotine causes cancer and other health risks. In fact, 53 percent of respondents in one study said they believe nicotine from combustible cigarettes is the leading cause of cancer.

FDA has acknowledged that nicotine can be “delivered through products that represent a continuum of risk,” and it has cited tobacco products “that must be lit and burned to use them” as the most harmful. But FDA has yet to approve a product standard that allows companies to advertise the reduced harm associated with their non-combustible tobacco products.

The warning on smokeless tobacco and snus products has contributed to Americans’ misperception of the harm associated with nicotine consumption. One study found that the use of a “not a safer alternative” warning “may be susceptible to misinterpretation, especially in the absence of information expressing differential product harms.”

As the regulatory authority over tobacco products, FDA is tasked with ensuring the public receives accurate, science-based information. By denying tobacco companies the ability to advertise the potential reduced harm of smokeless tobacco products, FDA is preventing access to information that could significantly benefit public health. A 2006 “study funded by the National Cancer Institute estimated four million American smokers would switch to snus if they were informed about the vastly lower risks of that product.”

**Policy Implications**

FDA should approve the modified risk tobacco product application for Camel Snus because FDA has already acknowledged the continuum of risk among tobacco products. Approving this application would finally allow manufacturers to inform consumers of the reduced health risks associated with smokeless tobacco products.
Data from Sweden and the United States provides indisputable evidence that smokeless tobacco is significantly less harmful than combustible cigarettes. Tobacco product users must be made aware of the continuum of health risks associated with all forms of tobacco. FDA should approve the modified tobacco risk product application for Camel Snus so that the public can more easily make well-informed health decisions.

Sincerely,

Lindsey Stroud
State Government Relations Manager
The Heartland Institute

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4 Brad Rodu et al., supra note 2, p. 11.
9 Raymond Niaura, supra note 6.
10 Brad Rodu et al., supra note 2, p. 13.


16 FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death,” U.S. Food and Drug Administration, July 28, 2017, [https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm).

