



January 23, 2017

Stephen Ostroff, M.D.  
Acting Commissioner  
Division of Dockets Management (HFA305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
RE: Docket No. FDA-2016-N-2527

Dear Commissioner Ostroff:

The undersigned groups submit these initial comments in the above-designated docket concerning the Proposed Rule entitled “Tobacco Product Standard for N-nitrosornicotine Level in Finished Smokeless Tobacco Products.”

**The Proposed Rule is an unprecedented step to reduce cancer deaths, protect public health and save lives by proposing the first-ever regulation governing the design and contents of tobacco products.**

The Proposed Rule will reduce the risk of cancer caused by smokeless tobacco products by requiring a reduction in the level of a potent carcinogen, N-nitrosornicotine (NNN), in all smokeless tobacco products sold in the United States.

Because the propose rule addresses a significant health threat, we respectfully request that the proposal not be delayed by 60 days. Because it is a proposed rule, the Administration will have sufficient opportunity to review the rule through the rulemaking process.

The Proposed Rule is supported by strong scientific evidence and would significantly benefit public health. As the proposal states, “NNN is a potent carcinogenic agent found in smokeless tobacco products and is a major contributor to the elevated cancer risks associated with smokeless tobacco.” The FDA estimates that, in the 20 years following implementation of its proposed product standard, approximately 12,700 new cases of oral cancer and approximately 2,200 oral cancer deaths would be prevented in the U.S. because of this rule. The FDA expects its proposed standard to also reduce the risk of esophageal cancer and states that it may also reduce the risks of other cancers such as pancreatic, laryngeal, prostate and lung cancer.

The scientific evidence is clear and beyond dispute.

This proposed rule marks the first time the FDA has exercised authority it received under a 2009 law, the Family Smoking Prevention and Tobacco Control Act, to establish product standards governing the design and content of tobacco products. The law authorized the FDA to require tobacco manufacturers to reduce or remove harmful constituents from tobacco products if doing so will benefit public health.

The evidence the FDA provided in support of its proposed rule establishes that 1) reduction in the level of NNN in smokeless tobacco products will substantially reduce the risk of cancer to smokeless tobacco users;

and 2) it is feasible for manufacturers to produce smokeless tobacco products that greatly reduce this risk, and in fact, there are already products on the market with very low levels of NNN.

NNN is part of a class of carcinogens called tobacco-specific nitrosamines (TSNAs). The importance of reducing nitrosamine levels in smokeless tobacco products was underscored by the FDA's own findings in November 2015 when it authorized the marketing of eight snus smokeless tobacco products made by Swedish Match North America Inc. The FDA's scientific review found that these Swedish snus products contained significantly lower levels of NNN and another tobacco-specific nitrosamine called NNK. Specifically, the FDA found that these Swedish snus products contain "significantly lower levels of NNN and NNK compared to over 97% of the ST [smokeless tobacco] products currently on the U.S. market." The FDA then quantified the reduction in cancer risk from the lower levels of NNN alone:

Assuming persons who would have used other US ST products use these product[s] instead, an individual using these products with reduced NNN levels could decrease the excess cancer risk by 90% compared to use of moist snuff (market share: 82%), 67% compared to use of chewing tobacco (market share: 15%), 38% compared to use of United States (US)-style snus, and 92% compared to use of dry snuff.

These findings established that it is possible to produce smokeless tobacco products with far lower NNN content that would substantially reduce the risk of cancer for smokeless tobacco users. Tobacco manufacturers have the capability and the responsibility to do so. Research conducted by both independent academic researchers and the tobacco industry clearly demonstrates that nitrosamine levels in smokeless tobacco products, including NNN, can be controlled by careful selection of tobacco types and management of tobacco processing and storage procedures.

Many smokeless tobacco products sold in other countries have far lower TSNA content (including NNN) than most smokeless tobacco products sold in the United States. For example, in Sweden, because of established limits on TSNA levels in smokeless tobacco products, TSNA content is much lower compared to products sold in the U.S.

The FDA's proposal to limit the level of NNN in all smokeless tobacco products would substantially reduce the risk of cancer to users of smokeless tobacco. However, it will not make these products safe. It is critical that FDA exercise its authority to prevent tobacco companies from misleading the public about the health risk of these products.

The FDA and the Administration should move forward with the comment period and then quickly finalize the Proposed Rule without any delays. The science is clear. This rule will reduce the number of people who die from cancer. The fact that there are products already on the market that comply demonstrates that it can be accomplished.

Respectfully submitted,

American Academy of Pediatrics  
American Cancer Society Cancer Action Network  
American Heart Association  
American Lung Association  
Campaign for Tobacco-Free Kids  
Truth Initiative