



# THE FDA'S FIRST PROPOSED PRODUCT STANDARD

Public Comment Opportunity



On January 23, 2017, the U.S. Food and Drug Administration proposed a rule that would establish a product standard for smokeless tobacco that would dramatically reduce N-nitrosornicotine (NNN), a powerful carcinogen, in these products.

By requiring that the NNN content of smokeless tobacco products be no greater than 1 microgram per gram of tobacco, the FDA estimates that the proposal would save an estimated 2,200 lives and prevent 12,700 cases of oral cancer in the first 20 years after the rule is implemented.

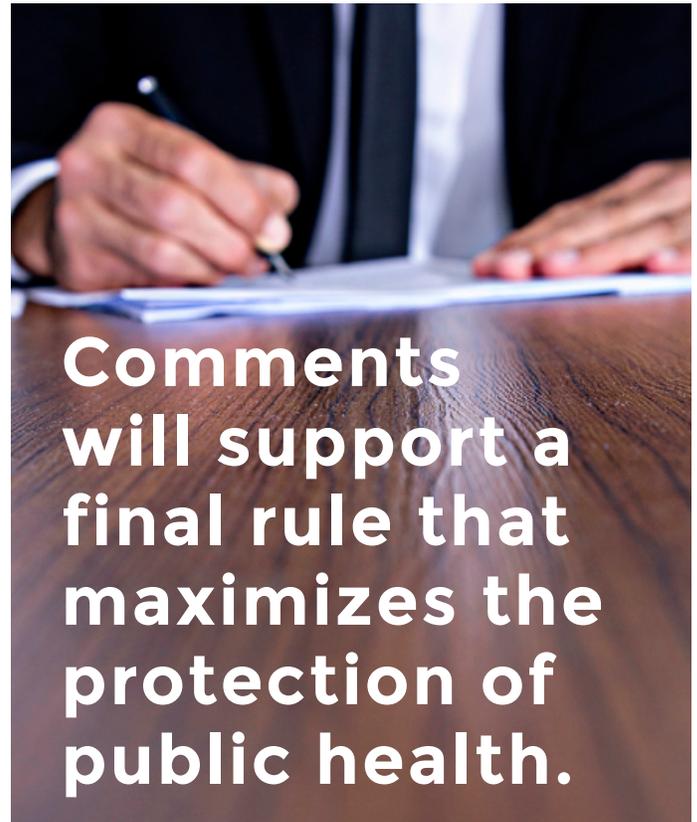
The FDA has broad power to set limits on the ingredients and constituents in finished tobacco products. To establish a tobacco product standard, the Tobacco Control Act requires that the FDA find that the standard is appropriate for the protection of the public health, taking into consideration scientific evidence concerning: **(1)** the risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products; **(2)** the increased or decreased likelihood that existing users of tobacco products will stop using such products; and **(3)** the increased or decreased likelihood that those who do not use tobacco products will start using such products. This is the FDA's first [proposed tobacco product standard](#).





The FDA has opened a [docket for public comments](#). Comments from the public health community will help the agency build an administrative record that will support a final rule that maximizes the protection of public health. In developing your comments, it is helpful to frame your comments to connect specifically with this standard. If possible, consider addressing the following topics:

- Information on the toxicity and the health effects of NNN, NNK, and other carcinogens found in smokeless tobacco products.
- Information on the relationship between NNN, NNK, and other carcinogens.
- Information on the production of NNN, methods of reducing NNN, the feasibility of such methods, and the likely impact on other carcinogens as a result of such methods.
- Information on the likely impact on initiation, cessation, dual and poly-use, and product switching as a result of the proposed standard.
- Information on usage patterns of smokeless tobacco including local level data.
- Information on risk perception related to product harm and reduced-harm products.
- Information on the likely impact on cancer rates and cancer mortality rates as a result of the proposed standard.
- Information on the appropriate testing methods to measure NNN levels.



For more resources related to this proposed rule, visit the [FDA Tobacco Action Center](#). In addition, Consortium attorneys are available to help you develop your comments and answer your questions about the public commenting process.