Kentucky Farm Bureau Federation

9201 Bunsen Parkway • P.O. Box 20700 • Louisville, KY 40250-0700
Telephone (502) 495-5000 • Fax (502) 495-5114 • kyfb.com

MARK HANEY
President
EDDIE MELTON
First Vice President
FRITZ GIESECKE
Second Vice President
DAVID S. BECK
Executive Vice President

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Division of Dockets Management (HFA-305)
United States Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2016-N-2527: Tobacco Product Standard for N-Nitrosonornicotine (NNN) Level in Finished Smokeless Tobacco Products

The following comments are submitted to Docket No. FDA-2016-N-2527, the proposed ***Tobacco Product Standard for NNN Level in Finished Smokeless Tobacco Products*** on behalf of Kentucky Farm Bureau Federation, Kentucky's largest general farm organization representing nearly 475,000 member families. Along with producing a diversity of agricultural commodities, Kentucky is the nation's largest producer of burley, dark air-cured and dark fire-cured tobacco. Tobacco production is an important economic crop for Kentucky's farmers and agricultural economy. The proposed rule to limit NNN levels in finished smokeless tobacco products, if finalized as currently drafted, could prove disastrous for many farmers and small business owners in the Commonwealth.

The proposed standard for NNN in finished smokeless tobacco products of 1.0 microgram/gram (μg/g) or less during any point through the product's labeled expiration date is technically unattainable with current technology. Further, the proposed rule combines all smokeless tobacco products, failing to differentiate between snus and United States-style moist snuff. These are very different products that utilize different types and sources of tobacco, and are manufactured in different ways. The rule also utilizes two different formulas to calculate the dry weight basis of NNN levels in finished smokeless products. Not only is the proposed level unattainable, the proposed rule adds confusion as to exactly how specific products are addressed and how the NNN level will actually be calculated.

Some comments already submitted to the proposed rule state that current plant varieties and technologies exist to allow smokeless products to meet the proposed NNN standard. Plant breeders continue work to develop new tobacco varieties that would have naturally lower NNN levels, but those varieties are still in development and not currently available commercially. Tobacco-specific nitrosamine (TSNA)

field research conducted in Kentucky and Tennessee over nearly a decade of research shows there is potential for TSNA growth during curing as well as during storage, fermentation and shelf-life of the product. Across roughly 900 samples, levels averaged about 1.57 parts per million (ppm) NNN in dark fire-cured samples and about 0.61 ppm in dark air-cured samples. Current formulation of U.S. moist snuff products is about 70 percent dark fire-cured leaf and 30 percent dark air-cured leaf, which would produce an average of about 1.3 ppm NNN (ppm is equivalent to μg/g). The only way to meet proposed FDA limits would be to change the ratio of dark fire-cured leaf to dark air-cured leaf in moist snuff blends creating a totally different product that may not be readily accepted by consumers.

Production practices also influence NNN levels in tobacco leaf. Farmers have been quick to adopt cultural practices such as crop fertilization, crop management and curing practices that help reduce NNN levels in the cured leaf, but as previously noted many other factors also influence the NNN levels in the finished smokeless product. It should be recognized that NNN is a naturally occurring substance in tobacco that can form not only during the growing and curing process, but also during the manufacturing process and even after the product has been packaged and being distributed for sale. Moisture and weather conditions play a critical role in final NNN levels. This is a very complicated issue, with several factors that affect NNN levels. Work to reduce NNN levels continues, but it is not at the point yet where the proposed level of 1 μg/g is attainable.

FDA alludes in the proposed rule that smokeless tobacco products should not be considered reduced risk products because they pose a significant cancer risk to users. However, statistics are clear that persons who switch from burned products such as cigarettes to smokeless products have a lower risk of developing serious health issues. The U.S. Surgeon General reported that cigarettes are the most hazardous and addictive of tobacco products. Per that report, cigarettes kill about 500,000 Americans annually. By FDA's own estimate, the smokeless products under this proposed rule kill an estimated 300 Americans per year primarily from mouth cancers. Tobacco farmers have never claimed smokeless products do not pose health risks, but studies have shown the risks are significantly lower. Smokeless products have also been proven to be effective in smoking cessation efforts. Can risks be lowered further? As newer varieties and technologies become available, risks can be lowered, but they are not available at this time.

Furthermore, President Trump's chief of staff, Reince Priebus, issued a regulatory freeze with a government-wide memo on January 20 to freeze all pending regulations until his appointees have an opportunity to complete a full review. With respect to the President's intent, we feel it is appropriate this rule be withdrawn for full administrative review.

The majority of leaf used in smokeless products is a combination of dark-air and dark-fire cured tobacco. Virtually all of the tobacco leaf utilized in United States-style moist snuff is grown in 23 counties in Kentucky and Tennessee. Forcing the industry to meet this standard at a time when it is technically impossible would have a devastating economic impact. Growers would lose a market for their leaf, manufacturers would be forced to recalculate formulas to develop a product meeting the standard but might not be acceptable to consumers, and retailers would lose product sales. Additionally, users of tobacco products might not have available a lower-risk alternative to cigarettes.

The FDA proposed rule on limiting NNN levels in finished smokeless tobacco is technically unachievable and we urge FDA, for a number of reasons outlined above, to withdraw the rule until varieties and technologies exist that will allow such standards to be economically met. Smokeless products do pose health risks, but their value as reduced risk products and smoking cessation aids must be considered as health advocates strive to reduce health issues relative to smoking. We appreciate the opportunity to submit these comments.

Sincerely,

Mark Haney

Mark Haney
President