

**Congress of the United States**  
**House of Representatives**  
**Washington, DC 20515-1701**

January 23, 2017

The Honorable Donald J. Trump  
President  
The White House  
1600 Pennsylvania Avenue, N.W.  
Washington, DC 20500

Dear Mr. President:

I write to bring to your attention a proposed rule (21 CFR Part 1132) that, if finalized, will have a devastating economic impact to the farmers and communities in my district. As I understand, FDA has proposed a tobacco product standard for N-nitrosornicotine (NNN) levels in finished smokeless tobacco products. FDA's proposed rule would require a standard for NNN of 1 part per million (ppm), a standard that is technically unachievable. The farmers in my district should not have to face the major economic uncertainty this rule creates while leadership at the agency changes in the weeks and months ahead. For this reason, I respectfully request that this proposed rule be withdrawn.

This proposed product standard would directly impact the dark tobacco (both air-cured and fire-cured) that is used in smokeless tobacco products. Kentucky farmers in my district grow almost all of the dark tobacco in the U.S. with the majority of growth concentrated within a 50 mile radius of Hopkinsville, KY and some additional growth in Tennessee. According to USDA, dark tobacco production in the U.S. totals around 24,000 acres with a cash value of approximately \$173 million per year. About 1,200 American farmers grow dark tobacco in about 8,000 barns/curing structures.

Under the Family Smoking Prevention and Tobacco Control Act, any tobacco product standard established by FDA must be technically achievable and consider the economic impact to domestic tobacco farmers and tobacco manufacturers. A 1 ppm standard to NNN is not technically achievable for U.S. smokeless tobacco products. Agronomic variability, including relative humidity during curing, is the largest contributor to tobacco-specific nitrosamines, including NNN, in tobacco on the farm. Because tobacco farmers cannot control changes in the weather, it is not achievable to meet the 1 ppm standard on an annual basis.

Rather than issue a proposed rule and ask for comments after the fact, FDA should have first asked for public comment by way of an Advance Notice of Proposed Rulemaking. Doing so would have allowed important voices, like those of the American farmers who will be

affected, to be heard before the agency devised its proposal. Our farmers in fact have important information to share on a range of issues, including the impact of implementing changes to growing and curing practices that FDA is suggesting, and the economic impact to them and their communities if an unachievable standard is ordered.

In addition, any product standard should be structured so as not to advantage foreign-grown tobacco over domestically grown tobacco. Since almost all dark tobacco used in domestic smokeless tobacco products is sourced from U.S. farmers, establishing a standard that is not achievable in the U.S. will have an overwhelming negative impact on domestic tobacco farmers and manufacturers.

I urge the Administration to consider the economic impact and the effect to the farmers in my district of this proposed rule and withdraw it immediately.

Sincerely,

A handwritten signature in black ink that reads "James Comer". The signature is written in a cursive style with a large, prominent initial "J".

James Comer  
Member of Congress

CC: The Honorable Tom Price, Nominee for Secretary of Health and Human Services  
Senator Mitch McConnell, Majority Leader  
Senator Rand Paul