

Ryan F. Quarles
Commissioner



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Kentucky Department of Agriculture

March 6th, 2017

Honorable Tom Price, M.D.
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

Dear Secretary Price:

On January 19, 2017, in the late hours of the administration of President Barack Obama, the Food and Drug Administration (FDA) published in the Federal Register a proposed rule entitled "Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products" (21 CFR Part 1132). This rule, as proposed, will have a devastating effect on both farmers and business people across Kentucky. According to the Family Smoking Prevention and Tobacco Control Act, any tobacco product standard must consider the economic impact to domestic tobacco farmers and tobacco manufacturers. It further states that a product standard must be technically achievable. It is our belief that the FDA did not accurately estimate the economic impact or costs of this proposed regulation, nor do we feel that the product standard is realistic or achievable.

According to data from the U.S. Department of Agriculture (USDA), Kentucky has approximately 1,200 farmers that grow 24,000 acres of dark tobacco. This dark tobacco has an approximate annual cash value of \$173 million. The negative economic impact of this proposed rule will be devastating if implemented. The fact is that limiting the N-Nitrosornicotine level in finished smokeless tobacco products to one part per million is not realistic or achievable for numerous reasons. This product standard, if approved, would in fact ban the sale of smokeless tobacco products in the United States.

It is our hope and request that the FDA will withdraw this proposed standard that has a such far reaching negative impact on our farmers and businesses. Further, it would be better to bring together all of the stakeholders to promulgate a new standard that is both realistic and achievable for all parties without creating a devastating economic impact. If you or your staff have any questions or require any additional information, please feel free to contact me.

Thank you again for your consideration of this request.

Sincerely,

A handwritten signature in blue ink that reads "Ryan F. Quarles".

Ryan F. Quarles

JWM/LCT

