Director Mitch Zeller  
U.S. Food and Drug Administration  
Center for Tobacco Products  
Office of the Center Director  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  

Dear Director Zeller:

Thank you for your hard work in handling the many Pre-Market Tobacco Applications (PMTAs) submitted to the Food and Drug Administration (FDA) by small vapor businesses. In an effort to better understand your PMTA intentions, we are requesting clarification specifically related to PMTAs filed by small businesses with potential deficiencies.

It is our understanding that these businesses have participated in the federal regulatory process in a good faith effort to comply with recent FDA PMTA guidelines. However, COVID-19 has placed well-documented and significant limitations on laboratory testing, which is necessary for full compliance with PMTA guidelines. Additionally, the exceptional cost, and the backlog of over 1.7 million PMTA applications puts nearly 14,000 responsible small vaping businesses in a vulnerable position. Many are at risk of permanently closing down their operations without some sort of temporary exculpation while FDA responds to the issues mentioned above.

As you are aware, the independent vapor industry functions quite differently than that of the large tobacco industry. The bigger manufacturers rely largely on a network of convenience stores to sell their vapor products. The independent vapor industry largely manufactures lower concentration nicotine vaping liquids sold in dedicated vape shops that are staffed by individuals with specialized training. Additionally, vape shops typically do not allow minors to enter their stores and ensure extensive age verification protocols that differ from convenience stores.

Unlike the large tobacco companies, nearly 14,000 small vape shops are in danger of going out of business if the FDA does not delay or make adjustments to their PMTA guidelines. These small businesses support 160,000 jobs and produce an economic impact of over $24 billion. In the interest of the economic health for small businesses across the nation, we ask that you work with these small vapor businesses to find a reasonable solution to the problems arising from the PMTA requirements.
Thank you for your consideration as you attempt to provide stability and practicable resolutions in the FDA regulatory process. We look forward to your earliest response.

Respectfully,

[Signature]

Debbie Lesko
Member of Congress

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Matt Gaetz
Member of Congress