



The Honorable Janet Woodcock
 Acting Commissioner
 U.S. Food and Drug Administration
 10903 New Hampshire Avenue
 Silver Spring, Maryland 20993

June 31, 2021



Dear Acting Commissioner Woodcock:

On behalf of millions of taxpayers and consumers across the United States, we, the undersigned 23 organizations, believe that, in the interests of public health, adult access to safe e-cigarette products must be maintained in order to reduce cigarette consumption nationwide and save millions of lives.



A substantial body of scientific evidence suggests these products save lives by reducing the use of traditional combustible tobacco products. Pulling e-cigarettes and other vapor products from shelves will harm consumers and small businesses. Therefore, **we urge you to pursue a court-ordered extension to allow vaping products to remain available to adult consumers while undergoing their premarket review, as requested by the Small Business Administration (SBA) Office of Advocacy on June 7.**



While we recognize the Food and Drug Administration (FDA) has promised to exercise discretion in enforcement action, this does not provide the degree of certainty necessary for businesses who have complied with all relevant regulations and have not received authorization due to processing delays by the FDA. If an extension is not granted, there could be devastating consequences for businesses, particularly small businesses. Furthermore, any potential reduction in the supply of safe alternatives to tobacco could have a negative impact on public health across the United States and lead to an increase in tobacco-related mortality.

The FDA requires manufacturers and importers of electronic nicotine delivery systems (ENDS), also known as e-cigarettes or vapor products, to submit a premarket tobacco product application (PMTA). The application must demonstrate to the agency, among other things, that the marketing of the e-cigarette or vapor product would be appropriate for the protection of the public health. Applications for products on the market were due September 9, 2020, with enforcement to commence against unauthorized products from September 9, 2021. Manufacturers have submitted millions of official PMTA applications. However, due to the significantly higher than expected volume of applications, it is highly likely that the FDA will be unable to process all applications prior to the deadline.

In addition, the FDA has withdrawn the final rule published January 19, 2021, which declared that each product must be “appropriate for the protection of the public health” in light of the risks and benefits of the product to the general population. As a result, there is no final rule in place governing the PMTA process and therefore it is possible that a significant number of products may be removed from the market





following the deadline. Millions of consumers who depend on ENDS products for their health and thousands of businesses who depend on these products for their livelihood are threatened by this needless bureaucratic uncertainty. The only sure way to avert a disastrous outcome is for the FDA to obtain a court order allowing it to extend the existing moratorium on enforcement by another year.



Should the FDA choose not to do so, we encourage you, in lieu of case-by-case enforcement, to publicly declare that the agency will not enforce the removal of **any** products that have submitted a timely PMTA application while such application is still under review. This compromise solution would be an effective, equitable, and simple way to provide certainty to the millions of consumers and thousands of sellers of ENDS products.

The PMTA timeline has been changed before. Further delay is appropriate and consistent with regulatory precedent. Last April, a federal judge concurred with the FDA and allowed the PMTA deadline to be modified. A significant motivation behind this extension was the FDA's expectation that they would receive thousands of PMTA applications and would be unable to fully process all of them by the previous deadline. The agency has received more than 6 million applications, with each application containing thousands to millions of different supporting documents, ensuring that there is a near-zero chance of all PMTA applications being processed on time. The FDA itself has agreed with this assessment. Mitch Zeller, Director of the Center for Tobacco Products, has said publicly that PMTA applications are being reviewed in order of market-share, with the most popular products being reviewed first. Maintaining the September 9, 2021, deadline could disproportionately affect small businesses and impact tens of thousands of jobs.



The vaping industry, unlike many others, was created by small businesses, and these same small businesses continue to drive innovation in the market. As noted in SBA's letter:



“Small businesses drive the American economy, with approximately 99.9 percent of all firms being classified as small. The vaping industry is a perfect example of that statistic. Small businesses created the industry and have been the drivers of the industry's major innovations. While the Census Bureau's Statistics of U.S. Businesses does not report data specifically on the vaping industry, the data show that well over 90 percent of tobacco stores (NAICS 453991) are small. According to industry sources, there are approximately 14,000 ENDS firms located across the country, and there are over 20,000 establishments listed under 'Vape Shops & Electronic Cigarettes' in the Yellow Pages.”



Without these entrepreneurs, the vape industry will be consolidated into a few large corporations, causing prices to rise and consumer choice to decrease.



The science on ENDS is clear. Vaping is at least 95% less harmful than traditional combustible cigarettes and is the most effective available method of smoking cessation, more than twice as effective as traditional nicotine replacement therapies



like patches or gum. This is why vaping has been endorsed by more than 60 of the world’s leading public health organizations as safer than smoking and an effective way to help smokers quit.

When e-cigarettes entered the market in 2003, the U.S. adult cigarette smoking rate was 21.6%. Due in no small part to increased access to vaping, the U.S. adult smoking rate has plummeted to 13.7% as of 2018. A large-scale analysis from Georgetown University Medical Center estimates that 6.6 million American lives would be saved if a majority of cigarette smokers made the switch to vaping. Furthermore, the analysis finds, increased vaping use among cigarette smokers would “reduce health disparities,” since smoking rates are highest among those with lower income and education, and this reduction would “translate directly into lower medical costs” and “an improved quality of life.”



For these reasons, we strongly urge you to follow the recommendation of the Small Businesses Administration and pursue a court-ordered extension as soon as possible to modify the current September 9, 2021, PMTA deadline. Tens of thousands of jobs and millions of American lives depend upon it.

Sincerely,

Grover Norquist
President
Americans for Tax Reform

Ryan Ellis
President
Center for a Free Economy

Christopher G. Sheeron
President
Action for Health

Andrew F. Quinlan
President
Center for Freedom & Prosperity

Marty Connors
Chair
Alabama Center-Right
Coalition

Yael Ossowski
Deputy Director
Consumer Choice Center

Krisztina Pusok
Director
American Consumer Institute

Tom Schatz
President
Council of Citizens Against
Government Waste

Amanda Wheeler
President
American Vapor
Manufacturers Association

James Taylor
President
The Heartland Institute

Brent Wm. Gardner
Chief Government Affairs
Officer
Americans for Prosperity

Mario H. Lopez
President
Hispanic Leadership Fund



**TAXPAYERS
PROTECTION
ALLIANCE**

Julie Gunlock
Director, Center for Progress
and Innovation
Independent Women's Forum

Seton Motley
President
Less Government

Kim "Skip" Murray
Specialist
Minnesota Smoke-Free
Alliance

Douglas Carswell
President & CEO
Mississippi Center for Public
Policy

Tim Jones
Fmr. Speaker, Missouri House
Missouri Center-Right
Coalition

Stefan Didik
Executive Board Member
Neighborhood Business
Alliance

Lorenzo Montanari
Executive Director
Property Rights Alliance

Paul Gessing
President
Rio Grande Foundation

David Morris
Vice President
Smoke-Free Alternatives
Trade Association

Lindsey Stroud
Director, Consumer Center
Taxpayers Protection Alliance

Casey Given
Executive Director
Young Voices

