U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
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October 13, 2020

VIA ELECTRONIC SUBMISSION

The Honorable Stephen M. Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Re: Docket Number FDA-2020-P-1797, Citizen Petition for Extension of Premarket Tobacco Product Application Filing Deadline Due to the COVID-19 Pandemic

Dear Commissioner Hahn:

The Food and Drug Administration's (FDA) final Deeming Rule requires manufacturers of deemed tobacco products to submit their products to the agency for approval before those products can be introduced into the market. On September 25, 2019, the FDA published a proposed rule titled *Premarket Tobacco Product Applications and Recordkeeping Requirements*.[1] Attached to this comment letter is the Office of Advocacy's (Advocacy) public comment letter on that proposed rule. The premarket tobacco product application (PMTA) rule has yet to be finalized. For most electronic nicotine delivery systems (ENDS) products, the only approval pathway available is the PMTA.

The timeline for PMTA compliance has been adjusted several times. As an outcome of the American Academy of Pediatrics litigation against the FDA, the United States District Court for the District of Maryland set the PMTA compliance date for May 12, 2020.[2] On March 30, 2020, the Government requested under Fed. R. Civ. P. 60(b) that the court extend that deadline because of the "exceptional and unforeseen" circumstances of the current pandemic.[3] On April 22, 2020,

[1] 84 Fed. Reg. 50,566 (Sept. 25, 2019).

[2] *American Academy of Pediatrics, et al. v. FDA*, (*AAP v. FDA*) Case No.: 8:18-cv-00883-PWG (D. Md.) (Doc. 127).

[3] *Id.* (Doc. 175).

the court granted the Government's request, setting September 9, 2020, as the new PMTA compliance date.[4]

On August 24, 2020, several small ENDS manufacturers, retailers, and trade associations submitted a citizen petition under 21 C.F.R. § 10.30 and the Family Smoking Prevention and Tobacco Control Act.[5] Advocacy is concerned that many small businesses in the vaping industry will be forced to close without a further extension of the PMTA deadline and that many of the issues the FDA cited as reasons for an extension in March 2020 are still present today. This letter constitutes Advocacy's public comments in support of the citizen petition.

I. Background

A. The Office of Advocacy

Congress established Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such, the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration.

B. Citizen Petition for Extension of Premarket Tobacco Product Application Filing Deadline Due to the COVID-19 Pandemic

The Government's request in March of this year to extend the PMTA deadline was rooted in the pandemic and its effect on the ENDS industry. Director of the FDA Center for Tobacco Products Mitchell Zeller submitted a declaration in support of extending the PMTA deadline, citing, *inter alia*, delays in laboratory testing, environmental assessments, and supplier responses; travel restrictions; and employee health concerns.[6] Many of the reasons cited in the Government's request for an extension of the May 2020 deadline still exist today. Indeed, on October 2, 2020, Health and Human Services Secretary Alex M. Azar, II, renewed his January 31, 2020, declaration that COVID-19 is a public health emergency.[7]

II. Advocacy's Small Business Concerns

Advocacy has two chief concerns if the FDA does not grant the vaping industry's citizen petition requesting an extension of the PMTA deadline.

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[4] *Id.* (Doc. 182).

[5] https://beta.regulations.gov/docket/FDA-2020-P-1797 (last visited October 2, 2020).

[6] *AAP v. FDA*, Supplemental Declaration of Mitch Zeller (Doc. 175-1).

[7] https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx (last visited October 5, 2020). Secretary Azar also renewed his January 2020 declaration on April 21 and July 23, 2020.

A. Many Small Businesses Will Close Without a PMTA Deadline Extension

Small businesses drive the American economy, with approximately 99.9 percent of all firms being classified as small.[8] 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 publish data specifically on the vaping industry, the data shows 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. As of August 31, 2020, there are over 400 million deemed tobacco products listed with the FDA.[9] As of June 2020, the FDA had received only 650 PMTA applications total.[10] Since Secretary Azar's declaration of COVID-19 as a public health emergency, only 218 PMTA applications have been filed.[11] The numbers are clear: more time is necessary.

Advocacy has heard from many small businesses in the vaping industry about the effects the pandemic has had on them. Even before the pandemic, the PMTA process was complex, overly burdensome, and costly for small businesses. The pandemic has increased those burdens. According to industry sources, revenues are down anywhere from 25 to 60 percent since the start of the pandemic. Because many, if not most, of the businesses in the vaping industry were not declared essential businesses, they were completely closed for up to two months under State lockdown orders. During these government-mandated closures, no PMTA work could be completed. For those small businesses that have reopened, many have had employees elect not to return to work because of the pandemic, which means there are even fewer people to cover the day-to-day business operations and preparation of a proper PMTA. One small business informed Advocacy that it had been working on a PMTA application since January but was only halfway done. This small business has three employees that will be unemployed if the PMTA deadline is not extended. These are the experiences of most of the small businesses throughout the industry. Simply put, the pandemic has only exacerbated the process for them to submit PMTAs.

B. The Reasons for the Government Requesting a PMTA Deadline Extension in March 2020 Have Not Abated

COVID-19 has impacted the entire globe. Our country has been living under a declared public health emergency for the last ten months. The pandemic has disrupted our lives and our livelihoods. The request for a deadline extension in March 2020 was necessary; that same

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[8] https://cdn.advocacy.sba.gov/wp-content/uploads/2019/09/24153946/Frequently-Asked-Questions-Small-Business-2019-1.pdf (last visited October 5, 2020).

[9] https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-preparations-september-9-submission-deadline (last visited October 5, 2020).

[10] https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&id=%20CTP-OS-total-PMTA-since-Program-Inception (last visited October 5, 2020).

[11] *Id.* There is no available information on the number of PMTAs filed over the past several months of the pandemic. The FDA's data is current as of June 30, 2020.

necessity holds true today. Many of the issues the agency cited as reasons for the extension are still problematic for small businesses now. On top of the mandatory closures, losses of revenue, and reduction of workforces, small businesses cannot get information or products from vendors and cannot arrange for laboratory testing of their products. The issues arising from the multiple months of shutdowns and the number of employees who are still working from home have made it nearly impossible for small businesses to get the information they need to complete PMTAs. Although laboratories are agreeing to test industry products, some small businesses have been told that it will be sometime in 2021 before their products will be tested. With no immediate end in sight for the current public health emergency, the FDA should again petition the court under Fed. R. Civ. P. 60(b) for another extension of the PMTA deadline.

III. Conclusion

As the pandemic continues its grip on our country, indeed the world, it is imperative that the FDA do all that it can to help small businesses in the vaping industry comply with the PMTA process. Advocacy is concerned that many small vaping manufacturers and retail stores will go out of business if the PMTA deadline is not further extended. Additionally, because many of the issues that the FDA cited as reasons for an extension in March 2020 are still present today it is imperative that the agency grant the vaping industry's citizen petition and again request an extension of the PMTA deadline.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Charles Jeane at (202) 205-7168 or by email at charles.jeane@sba.gov.

Sincerely,

/s/

Major L. Clark, III
Acting Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/

Charles G. Jeane
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Copy to: Paul Ray, Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget