U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
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June 7, 2021

VIA ELECTRONIC SUBMISSION

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

Mr. Mitchell Zeller, J.D.
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Re: Extension of One-Year Moratorium on FDA Enforcement Actions Against ENDS Manufacturers with Timely Submitted Premarket Tobacco Product Applications and the FDA's Policy to Review Premarket Tobacco Product Applications by Market Share

Dear Acting Commissioner Woodcock and Director Zeller:

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] 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. There are timely submitted PMTAs for millions of ENDS products for the FDA to review, and the agency only has until September 9, 2021, to do so before the court-ordered one-year moratorium on FDA enforcement actions ends. The Office of Advocacy (Advocacy) writes to encourage the FDA to request an extension of the court-ordered one-year moratorium on FDA enforcement actions against manufacturers that timely submitted a PMTA

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

to the agency by September 9, 2020, and to reverse its policy of reviewing submitted PMTAs by market share to keep small manufacturers' products on the market.

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. Advocacy Encourages the FDA To Request an Extension of the One-Year Moratorium on FDA Enforcement Actions Against ENDS Manufacturers with Timely Submitted PMTAs and To Reverse Its Policy of Reviewing Submitted PMTAs by Market Share.

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 (the court) set May 12, 2021, as the PMTA compliance date.[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, the court granted the Government's request, modifying the PMTA deadline set forth in the court's July 11, 2019, remedy order to September 9, 2020.[4] Unchanged in the court's remedy order is the requirement that products with timely submitted PMTAs may "remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while the FDA considers the application."[5]

When the Court set the one-year moratorium of FDA enforcement actions against makers of new ENDS products that had timely submitted a PMTA, there were very few submitted applications, and the deadline was based in part on the FDA's anticipation that it would receive thousands of PMTAs to review. In actuality, the agency has received millions of PMTAs to review.

When the FDA requested an extension of the application submission deadline because of the pandemic, Center for Tobacco Products Director Zeller stated in his supplemental declaration that "[a]s of February 29, 2020, 30 premarket tobacco product applications are pending for electronic cigarette products."[6] In April 2021, it was reported that there were approximately 59,819 PMTAs accepted, which is the first phase of the application process, and approximately 28,127 filed PMTAs, the second phase of the process.[7] As of May 20, 2021, there is a list of over

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[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).
[4] *Id.* (Doc. 182).
[5] *Id.* (Doc. 127).
[6] *AAP v. FDA*, Supplemental Declaration of Mitch Zeller (Doc. 175-1).
[7] PMTA Progress By the Numbers, Hannah Prokop. (April 9, 2021). https://www.cspdailynews.com/tobacco/pmta-progress-numbers (last visited May 28, 2021).

6 million new ENDS products with timely submitted PMTAs on the FDA website.[8] Some submitted PMTAs contain over 2 million files, with each file containing multiple pages of content for review.[9] Reviewing all those products before the court-imposed moratorium on FDA enforcement actions ends on September 9, 2021, is a Herculean task that is most likely impossible. Indeed, the FDA itself has stated that the likelihood of it reviewing all the submitted applications by September 9, 2021, is low.[10]

Additionally, Director Zeller announced that the FDA was reviewing timely submitted PMTAs by market share. This means that larger ENDS manufacturers are more likely to have an approved PMTA by the September 9, 2021, deadline, and their products will remain on store shelves. The FDA's decision to prioritize the review of PMTAs submitted by larger ENDS manufacturers also means that small ENDS manufacturers are those that will be subject to FDA enforcement actions and removal of their products from the marketplace after September 9, 2021.

II. Advocacy's Small Business Concerns

Small businesses drive the American economy, with approximately 99.9 percent of all firms being classified as small.[11] 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. As of May 2021, the FDA lists over 6 million deemed tobacco products – most of them ENDS products – with timely submitted PMTAs.[12] The FDA has three months remaining to approve the PMTAs for all those products before the court-ordered one-year moratorium on agency enforcement actions ends.

The general understanding in the ENDS industry is that manufacturers of new tobacco products that do not have FDA approved PMTAs by September 9, 2021, will have to remove their products from the marketplace until the agency approves their PMTAs. Small ENDS manufacturers cannot afford to have their products pulled from store shelves while the FDA continues to review the timely submitted PMTAs for millions of ENDS products. Most small ENDS manufacturers do not have the resources to absorb the losses from having their products pulled from the marketplace for several months or more. Once the FDA orders small ENDS manufacturers' products removed from the market, those small businesses will close

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[8] Deemed New Tobacco Product Applications Lists. https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/deemed-new-tobacco-product-applications-lists#list%20of%20deemed. (last visited May 28, 2021).

[9] https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline (last visited June 4, 2021).

[10] *Id.*

[11] https://cdn.advocacy.sba.gov/wp-content/uploads/2020/11/05122043/Small-Business-FAQ-2020.pdf (last visited June 1, 2021).

[12] *See* footnote 8 *supra*.

permanently. Conversely, larger ENDS manufacturers often are diversified with multiple product lines and revenue streams and could afford for their ENDS products to be temporarily removed from the marketplace until their PMTAs are approved. Under the current FDA review policy, larger ENDS manufacturers will get their products approved before any small ENDS manufacturers do. Advocacy believes the FDA should more closely consider the burden its review policy is putting on small businesses and that small businesses should be prioritized in the review process. Such action would be in line with the American tradition of support for small businesses as announced in such statutes as the Regulatory Flexibility Act, as well as several executive orders and presidential memoranda.

For these reasons Advocacy encourages the FDA to request from the court another one-year moratorium of agency enforcement actions on ENDS manufacturers who have timely submitted PMTAs and await FDA approval of their applications. Advocacy also encourages the FDA to reverse its policy of reviewing PMTAs from those with the largest market share to those with the smallest. This would allow many more small businesses to keep their products on store shelves and remain a part of the industry they created.

III. Conclusion

While Advocacy understands and appreciates the monumental task before the FDA, it is imperative that the agency do all that it can to help small businesses in the vaping industry remain in the marketplace and a part of the industry they created. Advocacy is concerned that many small ENDS manufacturers and retail stores will permanently close if the moratorium on FDA enforcement actions is not extended for those who timely submitted PMTAs and are awaiting FDA approval of their applications. Additionally, reversing the order of review of submitted PMTAs from largest market share to smallest will enable more small ENDS manufacturers to keep their products in the marketplace after September 9, 2021.

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: Sharon Block, Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget