May 13, 2022

Ms. Michele Mital
Acting Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Enforcement of Premarket Tobacco Product Applications (PMTA) deadlines for Synthetic Nicotine products

Dear Director Mital:

The undersigned organizations write today to urge you to enforce the Congressionally-mandated deadlines for Premarket Tobacco Product Applications (PMTAs) for synthetic nicotine products and not allow any delays of those deadlines.

In the recent omnibus appropriations bill, Congress extended FDA's tobacco product authority to include synthetic nicotine products. As such, the law ensures that synthetic nicotine products are regulated in the same way that tobacco-derived nicotine products are regulated. Congress further granted synthetic nicotine products a transition period in which such products would be allowed to stay on the market until July 13, 2022, provided that they submit the required PMTA by the May 14, 2022 deadline set for such applications. Only products with an FDA marketing order can remain on the market, not subject to enforcement, after July 13.[1]

Shortly after the effective date of FDA's authority over synthetic nicotine products, an article appeared where several industry attorneys speculated that FDA would allow synthetic nicotine products to stay on the market while FDA reviews them.[2] Referring to how FDA treated enforcement of tobacco-derived e-cigarette PMTAs, one industry attorney said, "If you look at what FDA has done for products that are still pending past the September 2021 date, the FDA

[1] https://www.fda.gov/tobacco-products/ctp-newsroom/reminder-electronic-submission-premarket-applications-non-tobacco-nicotine-products-due-may-14

[2]Castronuovo, Celine. "Tobacco-free vapes to linger on shelves as FDA grasps new power". Bloomberg News. April 22, 2022

has not taken enforcement action against any of the products that are covered by still pending applications. They may take a similar approach here with synthetic nicotine products."

The court order that established the September 2020 deadline for submitting PMTAs for tobacco-derived nicotine e-cigarettes and other newly deemed products granted a one-year period during which new products with timely filed PMTAs could remain on the market. After that one-year period, ending in September 2021, products without a marketing order from FDA were to come off the market or be subject to FDA enforcement. The undersigned organizations have repeatedly written to FDA urging the agency to take enforcement action against the products still on the market past the court-ordered September 2021 deadline and we continue to urge FDA to do so.[3] Furthermore, we urge FDA to complete review of the pending applications in a timely manner. We also have sought, and received, further relief from the Maryland federal court in the form of an order requiring FDA to make regular status reports on its consideration of PMTAs for products with the largest share of the market.[4] As the court found, "… the popular products used by young people remain on the market unreviewed, which is inconsistent with the purpose of this Court's judgment."[5]

In writing today, we remind FDA that the deadlines applicable to synthetic nicotine products have been set by Congress, which clearly sought to prevent FDA from allowing products to illegally remain on the market for an indefinite period, as the agency has done for tobacco-derived nicotine products. Congress left no room for any delays in requiring PMTA applications or enforcement for synthetic nicotine products. As of July 13, 2022 when the transition period has passed, any delays in enforcement against those products are contrary to Congressional intent and the express language of the law. Specifically, the law states that

> END OF TRANSITION PERIOD. – Beginning on the date that is 90 days after the effective date…, a tobacco product…(including such a tobacco product that is the subject of a pending application under section 910 of the Federal Food, Drug and Cosmetic Act (21 U.S.C.387j)) is in violation of such section 910 if such tobacco product does not have [a marketing] order in effect.[6]

It is essential that FDA adhere to these statutory deadlines and enforce the law against synthetic nicotine products that remain on the market without the required orders after July

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[3] *See eg.* Letter to Janet Woodcock on "Immediate Need for FDA Decisions Denying PMTAs for Flavored E-Cigarettes" from American Academy of Pediatrics, et al. (September 24, 2021) https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2021_09_24_Letter-FDA-Deny-PMTAs-Flavored-E-Cigs.pdf; Letter to Mitchell Zeller on "Need for FDA action on premarket applications for flavored e-cigarette products," https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2022_01_14_Letter-to-FDA-re-need-for-action-on-flavored-products.pdf

[4] Letter Order and Revised Remedial Order, *American Academy of Pediatrics, et al. v. FDA,* Case 8:18-cv-00883-PWG (D.Md. April 15, 2022).

[5] *Id*. at 2.

[6] P.L. No: 117-103.

13. We urge FDA not to consider any delays in implementing and enforcing this new authority over products containing synthetic nicotine.

The law also states that synthetic nicotine products that were intended specifically to replace tobacco-derived nicotine products that have previously received a marketing denial order from FDA,[7] will not be allowed to stay on the market at all during the transition period. For example, products such as Vapor Salon's e-cigarettes, would not be able to take advantage of the transition period because that company, upon receiving its marketing denial order from FDA , immediately indicated that it was "switching to TOBACCO FREE NICOTINE…to be outside of the FDA's regulations…"[8]

Synthetic nicotine products come in a wide variety of flavors such as Cool Mint, Mango Tango, Grape, Banana Ice, and Blueberry Ice. These products are very popular among young people. In fact, the most recent National Youth Tobacco Survey found that among both high school and middle school e-cigarette users, Puff Bar, a disposable e-cigarette that switched to synthetic nicotine, was the most reported "usual brand".[9] One report out of Stanford University noted that by February of 2022, there were 150 products (oral pouches, gums, disposable e-cigarettes and e-liquids) marketed with synthetic nicotine,[10] highlighting the sheer number and variety of these products that are available. According to another report, synthetic nicotine e-cigarettes went from being essentially absent from the market in 2020, to being sold in two-thirds of U.S. vape shops in 2021, and accounting for 20% of sales in those stores, indicating the rapid growth of these products.[11]

Given that many of the products that use synthetic nicotine are doing so precisely to avoid FDA regulation in the first place, the agency should not consider any delays or extensions for PMTA submissions or allow these products to stay on the market beyond the July 13 deadline. Congress set those deadlines to protect public health – and young people in particular – and to ensure that all nicotine products are regulated.

FDA should review all synthetic nicotine PMTAs as expediently as possible. Further, FDA must not extend any transition periods, and must swiftly bring enforcement actions against products:

- That have not submitted a PMTA by May 14, 2022,
- That are not eligible to stay on the market during the transition period, or
- For which the transition period has passed.

FDA must uphold the law and use the regulatory and enforcement authorities granted to it to their fullest extent.

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[7] This denial of a transition period also applies to tobacco-derived products that simply switched to synthetic nicotine after FDA refused to file their application, or for which marketing orders were withdrawn.
[8] https://filtermag.org/fda-vaping-marketing-synthetic-nicotine/
[9] https://www.cdc.gov/mmwr/volumes/70/wr/mm7039a4.htm
[10] https://tobacco.stanford.edu/wp-content/uploads/2022/03/Synthetic_Nicotine-_WhitePaper_3-6-2022F.pdf
[11] https://www.nytimes.com/2022/03/08/health/vaping-fda-nicotine.html

Thank you for your consideration.

Sincerely,

American Academy of Family Physicians
American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco Free Kids
Parents Against Vaping E-cigarettes
Truth Initiative

CC: The Honorable Dr. Robert M. Califf, FDA Commissioner