Congress of the United States

Washington, DC 20515

June 8, 2023

Dr. Robert Califf
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

We write to express our great concern over the FDA's repeated delays in reviewing pending Premarket Tobacco Product Applications (PMTAs) and its failure to remove all illegal products from the market. As requested in two previous letters, we again implore FDA to continue to deny applications for all non-tobacco flavored e-cigarettes, and take aggressive enforcement action to remove illegal e-cigarettes from the market, including synthetic nicotine products. It is critical that the FDA pursue all avenues of enforcement to protect youth from e-cigarettes and we are concerned with the pace and breadth of actions being taken to date. As such, we also request the FDA's prompt response to the questions in this letter.

Youth e-cigarette use remains unacceptably high. The FDA and CDC's National Youth Tobacco Survey (NYTS) found that last year more than 2.5 million middle and high school students were current e-cigarette users. Data from the NYTS signals that youth are not only experimenting with e-cigarettes but are becoming addicted to them.

FDA was under a court-ordered deadline to complete review of pending e-cigarette applications by September 9, 2021. Yet, in its two most recent filings with the court, FDA has indicated that it will not finalize its review of products with the largest market share until December 2023. While FDA has completed its review of many e-cigarettes, reviews of thousands of PMTAs remain incomplete, including applications for many of the products with the largest market share that are most popular with youth, such as Juul, Reynolds's Vuse Alto, Smok, and Suorin. Completing these premarket reviews is an important way to protect youth from e-cigarettes. **As such, we urge FDA to meet its commitment to finalize its review of these applications no later than December 31, 2023**. With 14.1 percent of high school students reporting current e-cigarette use in 2022, further FDA delay is unacceptable.

Further, we appreciate that FDA has recognized the role that flavors play in attracting kids to tobacco products and that it has not authorized any flavored e-cigarettes to date. We agree with FDA's decision to deny applications for several menthol-flavored e-cigarettes since menthol, like other flavors, increases the appeal and use of e-cigarettes by youth. **As such, we urge you to continue to deny applications for all non-tobacco flavored e-cigarettes, including menthol,** given the risk that these flavored products pose to youth.

Finally, we remain troubled that FDA has failed to take sufficient enforcement action to remove illegal products from the market. We recognize the FDA has only authorized 23 e-cigarette products, yet thousands of youth-appealing flavored e-cigarettes remain available in stores across the country. Manufacturers may have never submitted applications to FDA or even had their

applications denied by your agency but continue to sell their unauthorized products. FDA's failure to aggressively clear the market of illegal products has the potential to undermine the entire product review process. More aggressive enforcement action is critically necessary as it is clear that FDA warning letters alone will not clear the market of illegal tobacco products. While FDA took a step in the right direction by partnering with the Department of Justice to seek injunctions against six e-cigarette manufacturers and to impose civil monetary penalties against four additional manufacturers, the impact will likely be limited given the small number and size of the manufacturers. **As such, the current widespread disregard for the law necessitates a more forceful response from FDA, and we urge the FDA to more fully utilize the critical enforcement tools at its disposal**.

The need for more aggressive FDA enforcement action is equally true for synthetic nicotine products. Congress included bipartisan language in the FY 2022 Consolidated Appropriations Act to clarify FDA authority over synthetic nicotine products and made explicit that synthetic nicotine products – even those with pending applications – could not remain on the market after July 13, 2022 without an FDA authorization. To date, no synthetic nicotine product has received a marketing order from FDA and yet synthetic nicotine products remain widely available on the market. **As such, we urge you to aggressively use the authority that Congress provided your agency and to remove all synthetic nicotine products from the market, including those with pending applications.**

Given the concerns outlined in this letter, we strongly urge the FDA to (1) expeditiously complete review of remaining e-cigarette PMTAs; (2) follow the science on the risks flavored e-cigarettes pose to youth and deny PMTAs for all non-tobacco flavored e-cigarettes, including menthol flavored products; and (3) increase enforcement actions against companies that make, distribute, and sell flavored products without a marketing order, especially products with a significant market share, or products that are most popular with youth.

In addition, we request that you provide prompt responses to the following questions:

1. Congress provided the FDA with clear authority to take enforcement actions against any tobacco product that has not received a marketing order. To date, FDA has only issued marketing orders for 23 tobacco-flavored e-cigarettes, yet thousands of flavored e-cigarettes remain on the market.
    a. Why is FDA not taking aggressive action to remove all e-cigarettes that have failed to obtain marketing orders from the market?

2. The FDA should take enforcement action against *any* product that does not have a marketing order, especially non-tobacco flavored products. The FDA has acknowledged that existing evidence demonstrates that flavored e-cigarettes pose a "known and substantial" risk to youth.
    a. Given this evidence, why is FDA exercising its enforcement discretion for any flavored e-cigarette?
    b. Which categories of e-cigarettes are receiving enforcement discretion from FDA and why?

c. What is the public health rationale for not taking enforcement action against e-cigarettes with a pending application? What about products that never submitted a premarket application?
d. What steps has FDA taken to identify e-cigarettes that are on the market illegally and what enforcement action has FDA taken against them?
e. Will FDA commit to taking immediate enforcement action to remove these products from the market?

3. The synthetic nicotine provisions enacted as part of the FY 22 Omnibus Appropriations bill clarified FDA's regulatory authority over synthetic nicotine products. After a short transition period that has long since passed, the legislative language makes clear that any synthetic nicotine product without a marketing order is illegal, regardless of whether it has a pending marketing application with FDA. Many of these products are highly popular with kids and FDA to date has not issued a marketing order for any synthetic nicotine e-cigarette.
    a. Why is FDA allowing these products to remain on the market?

Time is of the essence. Thank you for your attention to this urgent matter. Please provides prompt responses to these questions by June 23, 2023.

Sincerely,

Debbie Wasserman Schultz
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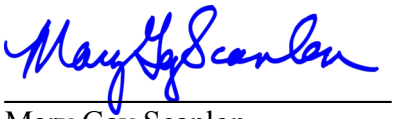

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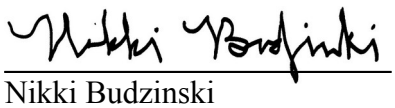

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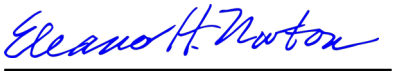

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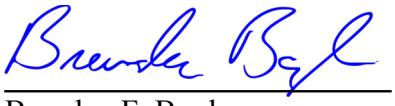

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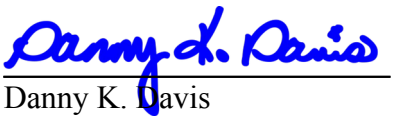

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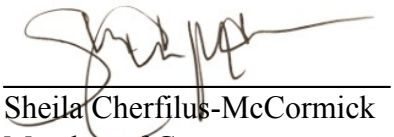

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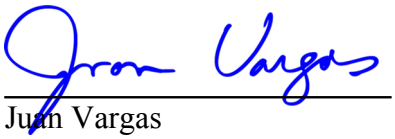

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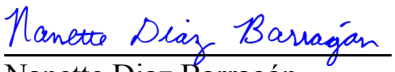

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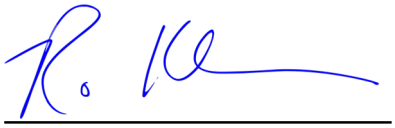

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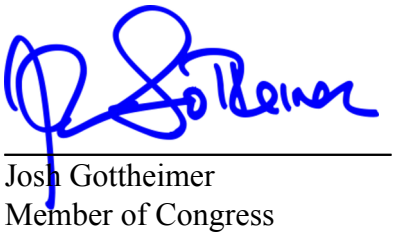

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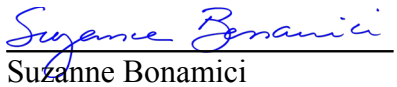

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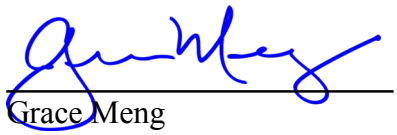

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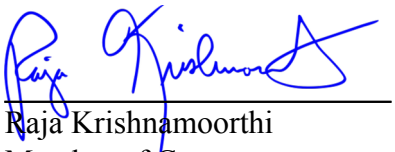

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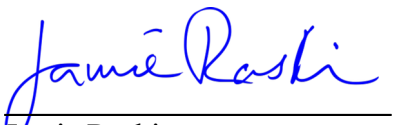

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