Congress of the United States
Washington, DC 20515

October 16, 2024

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

Dr. Brian King
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Commissioner Califf and Director King:

We write to express our serious 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. In 2024, the FDA and CDC's National Youth Tobacco Survey (NYTS) found that more than 1.6 million middle and high school students were current e-cigarette users. 42% of high school e-cigarette users reported frequent or daily use, indicating that youth are not only experimenting with but also becoming addicted to e-cigarettes. To protect youth from e-cigarettes, we again implore the FDA to prioritize this critical issue by (i) expeditiously finalizing review of pending PMTAs, (ii) following the science on the risks flavored e-cigarettes pose to youth and denying PMTAs for all non-tobacco-flavored e-cigarettes, including menthol-flavored products, and (iii) taking aggressive enforcement action against companies that make, distribute, and sell flavored products without a marketing order by removing illegal e-cigarettes from the market, including synthetic nicotine products. We also request the FDA's prompt response to the questions outlined in this letter.

First, we remain deeply concerned about the unacceptably high level of youth e-cigarette use, which is undermining the nation's efforts to reduce youth tobacco use and putting a new generation of kids at risk of nicotine addiction and serious health harms. Premarket review is a key public health protection and an important tool to reduce youth e-cigarette use, yet the FDA has still not completed its review of all e-cigarette products currently on the market, including products with a large market share, as well as nearly ten thousand synthetic nicotine products. In particular, the pending marketing applications for Juul products, which were filed more than four years ago, are disturbing given Juul's role in causing the youth e-cigarette epidemic and the continuing popularity of Juul's products among youth. While FDA has shown progress over the last year in reviewing e-cigarettes, this large volume of pending applications is troubling, especially considering that many of these products remain on the market illegally while the FDA continues to miss statutory and court-ordered deadlines, as well as its own projected dates, for completing these reviews. ***As such, we urge the FDA to avoid further delay and swiftly finish its review of all remaining applications.***

Additionally, we have serious concerns about FDA's decision to allow any flavored e-cigarette product, including menthol, to be on the market. In particular, FDA's decision this summer to authorize the sale of four menthol-flavored e-cigarettes made by NJOY was very disappointing and a significant departure from FDA's previous decisions to reject applications for flavored products. Flavors, including menthol, drive youth e-cigarette use, and the tobacco industry has a long history of using menthol flavoring to attract and addict kids. We cannot expect them to act responsibly in marketing menthol-flavored e-cigarettes. ***Given the appeal of these products to youth, we implore FDA to follow the science and deny all remaining marketing applications for flavored e-cigarettes, including menthol-flavored products.***

Further, we remain concerned that FDA has failed to take sufficient enforcement action to remove illegal products from the market. The FDA has authorized the sale of only 34 e-cigarette products – the only e-cigarette products that may be legally sold in the U.S. – yet thousands of youth-appealing flavored e-cigarettes remain available in stores and online. The tobacco industry continues to introduce additional illegal e-cigarette products without the required authorization, most of which are sold in kid-friendly flavors and deliver massive doses of nicotine. Making matters worse, manufacturers are now introducing e-cigarette products with video games and other smartphone-like features that make them even more appealing to kids. We are encouraged that FDA and DOJ recently launched a federal multi-agency task force to address the illegal distribution and sale of unauthorized e-cigarettes, an important first step in preventing youth use of e-cigarettes. Unfortunately, FDA's failure to aggressively clear the market of these illegal products has the potential to undermine the entire product review process. The task force must immediately utilize aggressive and comprehensive enforcement actions, particularly larger civil monetary penalties (CMP), product seizures, import restrictions, injunctive actions, and criminal prosecutions, to clear all unauthorized e-cigarettes from the market. ***To protect our kids, we urge the FDA to continue to work closely with the DOJ and other participating agencies to increase and pursue all avenues of enforcement to clear the market of these illegal products.***

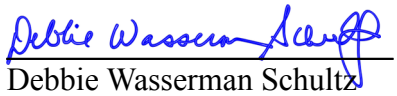
Finally, we request that you provide prompt responses to the following questions:

1. To date, FDA has only issued marketing orders for 34 e-cigarettes, but thousands of e-cigarettes remain on the market. FDA has stated that there is no safe harbor for products with pending applications and that "anyone who does not have authorization through the appropriate PMTA pathway is on the market illegally and at risk of enforcement." Yet we are not aware of FDA taking enforcement action to date against any product with a pending application, including Juul, which is highly popular with youth. As such, FDA should take enforcement action against *any* product that has not received a marketing order.
    a. *By what date can we expect FDA to take action against all unauthorized e-cigarette products currently on the market?*
    b. *What is the public health rationale for not taking enforcement action against any e-cigarette with a pending application?*
    c. *Why is FDA exercising its enforcement discretion for these products and which categories of e-cigarettes are receiving enforcement discretion from FDA?*
    d. Why isn't FDA taking enforcement action against Juul when it recently said their products can't be legally marketed?

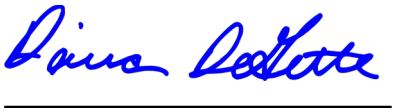
2. The Tobacco Control Act allows FDA to include multiple violations in a single proceeding and seek a maximum civil monetary penalty of up to $1.2 million per proceeding. Yet, when levying CMPs, FDA appears to only charge violators with a single violation with a maximum fine of $20,678, rather than for multiple violations.
    a. *Why doesn't FDA levy fines for multiple violations up to the statutory maximum?*
    b. *Given many manufacturers and distributors' blatant disregard for the premarket review process, will FDA commit to immediately levying CMPs for multiple violations?*
3. FDA has issued more than 680 warning letters to firms for manufacturing, selling, and/or distributing new tobacco products without marketing authorization. However, according to FDA's website, very few of these warning letters are followed up with response letters from the company or FDA close-out letters.
    a. *What percentage of firms that have received these warning letters have responded within 15 days describing their actions to address violations, as instructed?*
    b. *If FDA does not receive a response within this timeframe, what follow-up action does the agency take?*
4. Despite overwhelming evidence demonstrating that flavors drive youth e-cigarette use, FDA recently authorized the sale of four menthol-flavored e-cigarettes made by NJOY. According to FDA's technical project lead review of NJOY's PMTA, NJOY's own study found higher initiation and use of menthol-flavored NJOY products among youth compared to tobacco-flavored NJOY products, which underscores the higher risk that the menthol-flavored products pose to youth. *Given this evidence, why did FDA authorize these products?*
5. The synthetic nicotine provisions enacted as part of the FY22 Omnibus Appropriations bill clarified FDA's regulatory authority over synthetic nicotine products. The legislative language and bipartisan congressional intent make clear that any synthetic nicotine product without a marketing order is illegal, regardless of whether it has a pending marketing application.
    a. *Why is FDA not taking aggressive enforcement action to remove these products from the market, even if they have pending applications?*
    b. *Is FDA facing any specific challenges in removing these unauthorized products from the market?*
    c. *How many synthetic nicotine PMTAs are currently pending with the agency, how many synthetic nicotine PMTAs has FDA acted on to date, and how many synthetic nicotine PMTAs has FDA issued marketing denial orders for?*
    d. *By what date does FDA anticipate completing review of the remaining pending synthetic nicotine applications?*

Time is of the essence. Thank you for your attention to this urgent matter. Please provide prompt responses to these questions by November 15, 2024.

Sincerely,



Debbie Wasserman Schultz
Member of Congress



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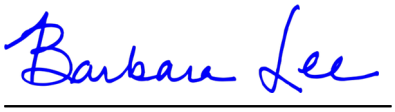

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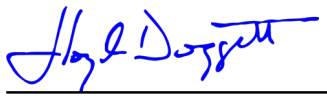

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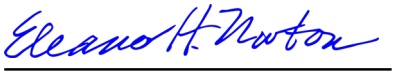

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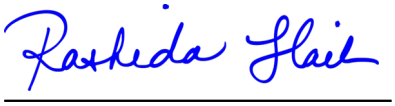

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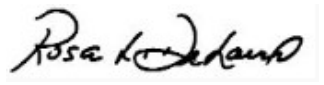

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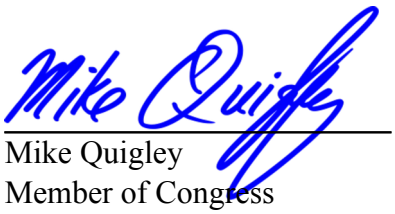

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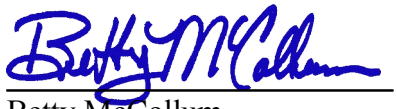

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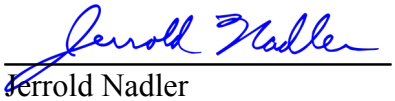

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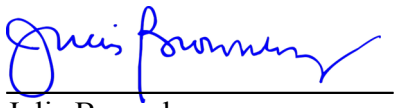

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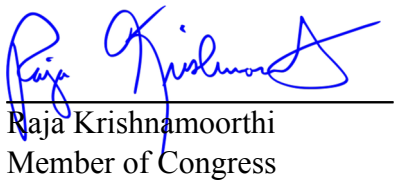

Raja Krishnamoorthi
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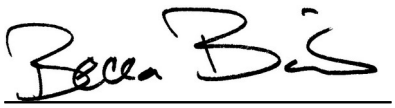

Becca Balint
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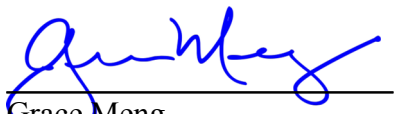

Grace Meng
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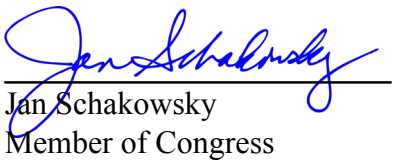

Jan Schakowsky
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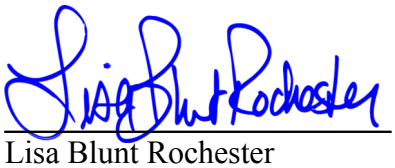

Lisa Blunt Rochester
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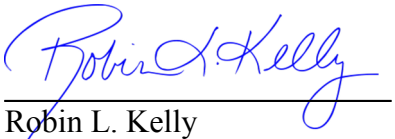

Robin L. Kelly
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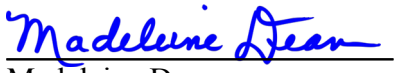
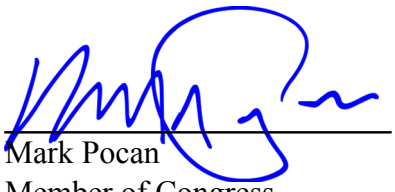


Madeleine Dean
Member of Congress



Mark Pocan
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Lois Frankel
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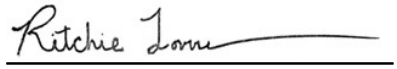
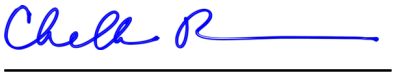


Ritchie Torres
Member of Congress



Chellie Pingree
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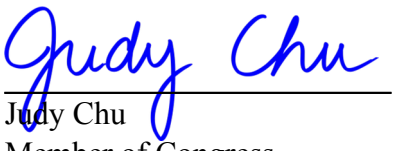
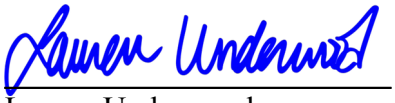


Judy Chu
Member of Congress



Lauren Underwood
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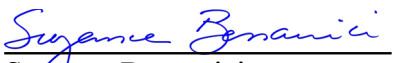

Suzanne Bonamici
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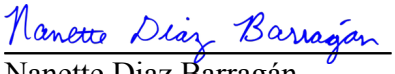

Nanette Diaz Barragán
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Darren Soto
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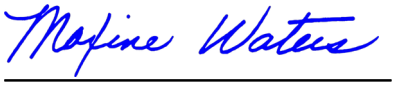

Maxine Waters
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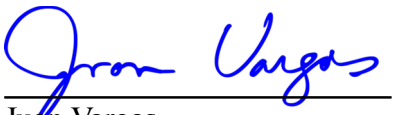
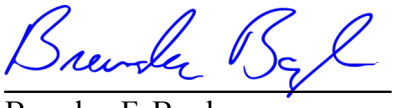
Melanie Stansbury
Member of Congress



Juan Vargas
Member of Congress



Brendan F. Boyle
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Angie Craig
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Adriano Espaillat
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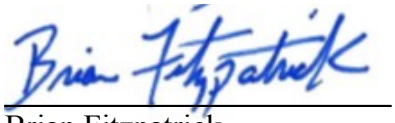
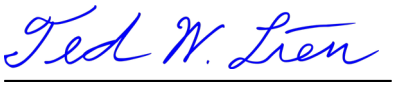
Andy Kim
Member of Congress



Brian Fitzpatrick
Member of Congress



Ted W. Lieu
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Dean Phillips
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Celeste Maloy
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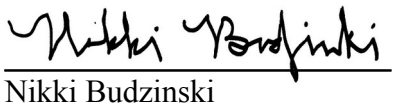
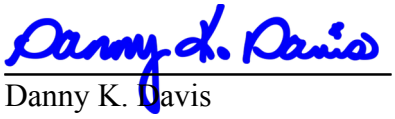


Nikki Budzinski
Member of Congress



Danny K. Davis
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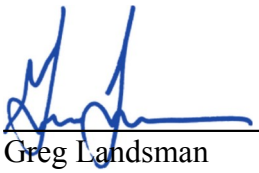

Greg Landsman
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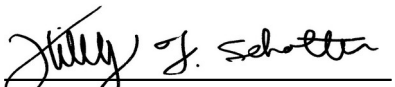

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Mike Levin
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