

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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September 10, 2021

Dr. Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock:

I am writing about the failure of the Food and Drug Administration (FDA) to complete its review of all premarket tobacco product applications (PMTAs) by the September 9, 2021, court-ordered deadline.

Yesterday, when FDA's PMTA decisions were due, the agency published an update informing the public that FDA would be ignoring its deadline. FDA stated that it would keep working on the applications and "issue [y]our decisions on a rolling basis."¹

In FDA's update, it pointed to the handful of inconsequential PMTAs that it has ruled on to date. None of those PMTAs relate to companies with significant market share. FDA's failure to rule on significant PMTAs is particularly troubling given your June 23, 2021, testimony to the Subcommittee that your top priority was ruling on PMTAs for companies with the highest market share. You said that FDA had prioritized review "by market share so that we have made sure that we are looking at the companies with large market shares that would have the most impact." You committed to "do everything I can to make sure that we have reviewed and finished all the high market share company applications because they will have the most impact on this problem." While you declined to name the high market share companies, you said, "I think there are only about five companies that have the vast majority of the market share, and then there are a very large number of small vape shops and other type of enterprises that constitute the rest."²

¹ Food and Drug Administration, *Perspective: FDA's Progress on Tobacco Product Application Review and Related Enforcement* (Sept. 9, 2021) (online at www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-tobacco-product-application-review-and-related-enforcement/).

² Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Subcommittee Hearing Offers Insight into Future of E-Cigarette Regulation* (June 23, 2021) (online at <https://oversight.house.gov/news/press-releases/subcommittee-hearing-offers-insight-into-future-of-e-cigarette-regulation/>); Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on "An Epidemic Continues: Youth Vaping in America"* (June 23, 2021) (online at <https://oversight.house.gov/legislation/hearings/an-epidemic-continues-youth-vaping-in-america>).

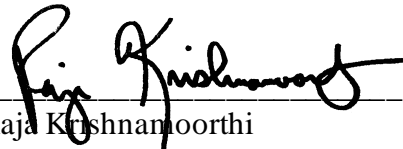
Despite your commitment, FDA has not ruled on any PMTAs for the five companies with the highest market share. Every day that FDA delays is another opportunity for a child to pick up a menthol JUUL and start on a path to addiction. In your words, “any flavor of e-cigarette left on the market is likely to encourage youth to start vaping.”³ If you are going to ignore your deadlines, we need an explanation.

You also told the Subcommittee that any product whose PMTA application FDA failed to rule on by September 9, 2021, could be subject to immediate enforcement action because those products are “only on the market under enforcement discretion by the FDA.”⁴ We request your confirmation that you will follow through and immediately start enforcing the law against every company selling e-cigarettes without a marketing order.

To assist the Subcommittee in its review of this matter, I request a staff briefing to occur on or before September 13, 2021, to address why FDA failed to meet its PMTA deadline, and subsequent briefings to occur once per week until FDA has ruled on every PMTA. Each briefing should address why FDA has failed to complete a review of all PMTAs, how it intends to accomplish completion of its review, specific timelines for doing so, and enforcement efforts against companies without marketing orders.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi
Chairman

Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member
Subcommittee on Economic and Consumer Policy

³ *Id.*

⁴ *Id.*