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December 6, 2021

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

Dear Acting Commissioner Woodcock:

We are writing about the status of the Food and Drug Administration's (FDA) progress in reviewing premarket tobacco product applications (PMTAs) from e-cigarette manufacturers.

Despite the September 9, 2021, court-ordered deadline for FDA to rule on all PMTA applications, FDA has yet to complete its review or issue rulings on the most significant applications. We are concerned that FDA may not be making adequate progress on its commitment to prioritize the review of the e-cigarette manufacturers with the largest market share.[1] Four out of the five manufacturers with the highest market share have yet to receive a decision, and the fifth, R.J. Reynolds, has only had part of its application ruled upon.[2]

On September 10, 2021, the Subcommittee wrote to you requesting a staff briefing to address why FDA failed to meet the court's deadline, and weekly briefings to follow until FDA rules on all PMTAs.[3] We appreciate that you have provided weekly briefings, however, we have not received any information about FDA's progress on the remaining applications. In addition, FDA has not indicated its intent to rule on these PMTAs in the foreseeable future. As a result, we are unable to determine whether FDA has made significant progress toward a resolution.

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[1] 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).

[2] Food and Drug Administration, *News Release: FDA Permits Marketing of E-cigarette Product, Marking First Authorization of Its Kind by the Agency* (Oct. 12, 2021) (online at www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency).

[3] Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, to Acting Commissioner Janet Woodcock, Food and Drug Administration (Sept. 10, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-09-10.RK%20to%20Woodcock-FDA%20re%20PMTAs.pdf).

When FDA granted R.J. Reynolds's application for its tobacco flavored Vuse product, it published a marketing order explaining its decision. That marketing order contained a progress report timeline reflecting when FDA completed each of the 26 steps that it undertakes when reviewing a PMTA application. For the Vuse application, these steps were completed over a span of 17 months, from May 18, 2020, to October 12, 2021.[4]

Table 1. Disciplines reviewed

Discipline	Cycle 1		Cycle 2	
	Reviewer(s)	Review Date	Reviewer(s)	Review Date
Engineering	Ryan Andress	5/18/2020	Ryan Andress	10/12/2021
Chemistry	Jikun Liu	5/19/2020	Jikun Liu	10/07/2021
Microbiology	David Craft	5/18/2020	Aimee Cunningham	10/12/2021
Toxicology	Steven Yee	5/18/2020	Thomas Hill	10/08/2021
Behavioral & Clinical Pharmacology	Mollie Miller	5/18/2020	Allison Kurti	10/12/2021
Medical	Lester Lacorte	5/19/2020	Lester Lacorte	10/08/2021
Epidemiology	Blair Coleman	5/19/2020	Jamal Jones	10/12/2021
Social Science	Katherine Margolis	5/18/2020	Andrea Ruybal	10/12/2021
Environmental Science	William Brenner	5/18/2020	Yasmin Termeh-Zonoozi	10/06/2021
OCE – Manufacturing/Lab	Lara Williams	5/19/2020	N/A	N/A
OCE – BIMO	Tara C. Singh	5/19/2020	N/A	N/A

Table 2. Consultations

Discipline or Office	Reviewer(s)	Review Date
Statistics	Ruben Montes de Oca	5/19/2020
OCE – DPAL	Julie Nguyen	5/19/2020
Tobacco Product Surveillance Team (TPST)	Susan Rudy	3/04/2021
OHCE	Emily Talbert	10/12/2021

Source: FDA

In order for us to understand FDA's progress on the remaining applications, by December 20, 2021, we request that you provide us with similar charts for each of the remaining applications showing which steps have been completed and when. FDA may redact the names of companies on each chart and may redact the names of its reviewers.

[4] Food and Drug Administration, Technical Project Lead Review of PMTAs, Vuse (Oct. 12, 2021) (online at www.fda.gov/media/153017/download).

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

Michael Cloud
Ranking Member
Subcommittee on Economic and
Consumer Policy