

ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

November 14, 2019

The Honorable Brett P. Giroir
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Giroir:

I write today regarding recent reports that JUUL Labs Inc. (JUUL) knowingly shipped and sold approximately one million contaminated mint-flavored e-cigarette nicotine pods.¹ According to an October 29, 2019, complaint filed by a former JUUL executive, JUUL allegedly knew the products were contaminated, yet did not warn consumers or issue a recall.²

In November 2018, in response to government pressure and public concerns over the youth vaping epidemic, JUUL announced the company would pull most of its flavored pods from retail stores, leaving mint- and menthol-flavored products on the shelves.³ According to the lawsuit, JUUL leaders subsequently pressured the “supply chain team and its suppliers...to produce more mint-flavored pods in order to make up for sales losses.”⁴ This allegedly “compromised the quality control measures, as the focus was on producing and selling mint-flavored pods at any cost, even when the product turned out not to be safe.”⁵ It is imperative that the Food and Drug Administration (FDA) investigate this allegation regarding contaminated products on the market if it has not yet done so.

¹ BuzzFeed, *Juul Shipped at Least a Million Contaminated Pods, New LawsUIT Says* (Oct. 29, 2019).

² *Id.*

³ New York Times, *JUUL Suspends Selling Most E-Cigarette Flavors in Stores* (Nov. 13, 2018).

⁴ Complaint at 36, *Breja v. JUUL Labs, Inc.*, No. 3:19-cv-7148 (N.D. Cal. Oct. 29, 2019).

⁵ *Id.*

Additionally, I am further alarmed by the alleged tactics JUUL utilized in seeking to promote mint-flavored products as a replacement to other flavors. According to the complaint, outside consultants assured JUUL that, “given its fruity flavor, [mint] would make up for any lack of sales of other flavored pods.”⁶ Indeed, according to the lawsuit, “the withdrawal of flavored pods from retail stores did nothing more than increase the demand for mint-flavored pods.”⁷ The complaint further states that while mint-flavored products had been one-third of JUUL’s pod sales in September 2018, following the removal of other flavored pods from retail shelves, mint-flavored pods soared to two-thirds of JUUL’s pod sales in February 2019.⁸

Given data from the Centers for Disease Control and Prevention indicating both mint- and menthol-flavored e-cigarette products as increasingly appealing to young people,⁹ I am concerned these actions may further increase the appeal of e-cigarettes to youth. In fact, in testifying before the Oversight and Investigations Subcommittee last month, former Acting Commissioner Sharpless stated that, “the data support mint and menthol being a significant problem. ...it’s been very popular with children.”¹⁰

Indeed, a study of e-cigarette use among U.S. youth published on November 5, 2019, found that the use of mint- and menthol-flavored e-cigarettes increased sharply after JUUL restricted the availability of other flavors.¹¹ In response to these and other findings, on November 7, 2019, JUUL announced that it would stop the sales of its mint pods, but their menthol products remain on the market.¹² Alarming, there is nothing to prevent JUUL from promoting menthol products to compensate for the lack of mint pod sales.

These recent accounts further underscore the concerns detailed in the letter I sent to the President on October 30, 2019, regarding reports that the Administration is reconsidering its promise to clear the market of non-tobacco flavored e-cigarette products, including mint and

⁶ New York Times, *Former JUUL Exec Alleges Company Shipped Tainted Products* (Oct. 30, 2019).

⁷ Complaint at 33, *Breja v. JUUL Labs, Inc.*, No. 3:19-cv-7148 (N.D. Cal. Oct. 29, 2019).

⁸ *Id.*

⁹ Food and Drug Administration, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019); Centers for Disease Control and Prevention, Dr. Anne Schuchat, *Testimony before the Committee on Energy and Commerce Oversight and Investigations Subcommittee* (Sept. 25, 2019).

¹⁰ Food and Drug Administration, Dr. Norman Sharpless, *Testimony before the Committee on Energy and Commerce Oversight and Investigations Subcommittee* (Sept. 25, 2019).

¹¹ Karen Cullen et al, *e-Cigarette Use Among Youth in the United States, 2019*, J. Am. Med. Assn. (Nov. 5, 2019).

¹² Wall Street Journal, *Juul to Stop Selling Mint E-Cigarettes* (Nov. 7, 2019).

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menthol flavors.¹³ It has now been nine weeks since the Administration announced it would be finalizing a compliance policy to “tackle the epidemic of youth e-cigarette use.”

These allegations and JUUL’s actions provide yet another reason why the Trump Administration should move quickly to issue its compliance policy to remove flavored e-cigarette products—including both mint- and menthol-flavors—from the market as originally announced.¹⁴ They also reconfirm why it is essential that FDA begin reviewing all Premarket Tobacco Product Applications (PMTAs) for e-cigarette products available on the market prior to August 8, 2016, as soon as possible. The delay in compliance deadlines for filing PMTAs has enabled e-cigarette products to remain on the market without sufficient regulatory review. I once again urge the Trump Administration to move swiftly to protect the public’s health and the well-being of our nation’s young people.

I respectfully request a briefing regarding FDA’s actions related to these allegations and their implications, an update on the timing and content of the previously announced flavored-product compliance policy, and FDA’s preparation for the May 2020 PMTA submission deadline for tobacco products on the market prior to August 8, 2016.

Thank you for your prompt attention to this matter. If you have any questions, please contact Jesseca Boyer and Jacquelyn Bolen of the Committee staff at (202) 225-2927.

Sincerely,

A handwritten signature in blue ink, appearing to read "Frank Pallone, Jr.", written in a cursive style.

Frank Pallone, Jr.
Chairman

¹³ Letter to Secretary Azar and Acting Commissioner Sharpless (Oct. 30, 2019).

¹⁴ Food and Drug Administration, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019).