FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

GREG WALDEN, OREGON
RANKING MEMBER

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

March 4, 2020

Mr. Ryan Nivakoff
Chief Executive Officer
NJOY, LLC
15211 North Kierland Boulevard, Suite 200
Scottsdale, AZ 85254

Dear Mr. Nivakoff:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, February 5, 2020, at the hearing entitled "Vaping in America: E-Cigarette Manufacturers' Impact on Public Health." We appreciate the time and effort you gave as a witness before the Subcommittee on Oversight and Investigations.

Pursuant to Rule 3 of the Committee on Energy and Commerce, members are permitted to submit additional questions to the witnesses for their responses, which will be included in the hearing record. Attached are questions directed to you from me and other members of the Committee. In preparing your answers to these questions, please address your responses to the member who has submitted the questions using the Word document provided with this letter.

To facilitate the publication of the hearing record, please submit your responses to these questions by no later than the close of business on Wednesday, March 18, 2020. As previously noted, your responses to the questions in this letter, as well as the responses from the other witnesses appearing at the hearing, will all be included in the hearing record. Your responses should be transmitted by email in the Word document provided with this letter to Benjamin Tabor with the Committee staff (benjamin.tabor@mail.house.gov). A paper copy of your responses is not required. Using the Word document provided for submitting your responses will also help maintain the proper format for incorporating your answers into the hearing record.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Mr. Tabor at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Attachment

cc: Hon. Greg Walden, Ranking Member
Committee on Energy and Commerce

Hon. Diana DeGette, Chair
Subcommittee on Oversight and Investigations

Hon. Brett Guthrie, Ranking Member
Subcommittee on Oversight and Investigations

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Vaping in America: E-Cigarette Manufacturers' Impact on Public Health"

February 5, 2020

Mr. Ryan Nivakoff, Chief Executive Officer, NJOY, LLC

The Honorable Frank Pallone, Jr. (D-NJ)

1. As of February 6, 2020, the Food and Drug Administration (FDA) is prioritizing enforcement with respect to the unauthorized marketing of closed-cartridge non-tobacco and non-menthol flavored products. On January 28, 2020, NJOY informed FDA it would be voluntarily suspending its non-tobacco and non-menthol flavored disposable products. However, NJOY has two menthol products currently available for sale ("Cool Menthol" Loop Pods and NJOY Daily "Menthol") that are both marketed as "Menthol with a vanilla essence." Do these products contain flavor components beyond menthol? Is it possible that consumers, including young people under the age of 21, may view these menthol products as having an additional vanilla flavor profile? Either way, why would these products not be subject to FDA's guidance or NJOY's voluntary suspension of certain disposable products?

The Honorable Diana DeGette (D-CO)

1. Do you expect that the guidance issued by FDA on January 2, 2020, and in effect as of February 6, 2020, will reduce youth use of NJOY's products or of e-cigarette products in general? Why or why not?

2. Do you believe FDA or other federal agencies have the resources (financial or otherwise) to monitor data and evolving trends with respect to youth use of e-cigarettes? If not, what more needs to be done?

The Honorable Brett Guthrie (R-KY)

1. Currently, the Food, Drug and Cosmetic Act limits the ability of the U.S. Food and Drug Administration (FDA) to disclose receipt of premarket tobacco product applications (PMTA).

    a. After May 12, 2020, what is your understanding of how distributors, retailers, and other relevant entities will be able to determine which products have a PMTA

submitted to FDA, and thus can remain on the market while under review, and which products do not have a PMTA submitted to FDA?

b. Are any regulatory or legislative changes necessary to help inform the public and enforcement authorities about which products will be allowed on the market after May 12, 2020?

2. During the summer of 2018, FDA conducted an enforcement blitz of retailers nationwide, resulting in more than 1,100 Warning Letters and approximately 130 civil monetary penalties being issued to retailers for underage sale of e-cigarettes. Those cases included the illegal sale of Logic, JUUL, Fontem, and JTI products to minors. As such, each company received a letter from FDA in September 2018 requesting a meeting with FDA and that each company submit a detailed plan to address and mitigate widespread use by minors.

   a. What was the result of your company's response to this request from FDA

3. In addition to the Customs and Border Patrol, does your company have a direct line of communication with other law enforcement entities for reporting illicit products?

   a. If so, has information that your company has provided to law enforcement resulted in criminal enforcement actions?

4. What does your company do to ensure the safety of the supply chain for your ENDS products?