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. Antoine Blonde
President
Fontem US, Inc.
1100 South Tyron Street, Suite 300
Charlotte, NC 28202

Dear Mr. Blonde:

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. Antoine Blonde, President, Fontem US, Inc.

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

1. The Food and Drug Administration (FDA) guidance issued on January 2, 2020, and in effect as of February 6, 2020, includes an exemption that allows disposable flavored e-cigarettes, such as Fontem's Vivid Vanilla and Cherry Crush disposable products, to remain on the market. Given the evidence that young people are drawn to non-tobacco flavored e-cigarettes, do you believe there is a risk that when flavored cartridge-based products are no longer available to them, youth may turn to using disposable flavored products? What is Fontem doing to proactively prevent and monitor youth use trends related to its flavored 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 Fontem'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?