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?**

   As Mr. Blonde testified, Fontem is complying with FDA's January 2, 2020 final guidance (the "FDA Guidance"), outlining the agency's enforcement priorities for electronic nicotine delivery systems ("ENDS"). The FDA Guidance's prioritization of enforcement against flavored, cartridge-based ENDS products does not apply to disposable products. In exempting disposable products from this enforcement priority, FDA cited data indicating that youth are most likely to use flavored, cartridge-based ENDS products.[1]

   Having said that, Fontem believes unequivocally that youth should not access ENDS products and none of its products – including its disposable products – are marketed to youth. Fontem is aware of the risks of youth access to ENDS products, which is why Fontem has implemented a robust youth access prevention program. As set forth in Fontem's previous responses to the Committee, Fontem maintains strict controls to ensure that its products are not sold to youth, including employing an online age verification software to prevent the sale of products online to consumers under the age of 21. Fontem also requires its retail partners to participate in the We Card Program or other comparable age verification programs, and the Company actively monitors the FDA Undercover Buy Inspections database to review reported violations. If Fontem learns that a retailer has engaged in conduct inconsistent with the Company's policies regarding youth access, Fontem takes action to address the issue, up to and including terminating that retailer as a partner. Fontem has also implemented strict marketing policies to ensure that its products are never marketed to youth, including prohibiting users under the age of 21 from following Fontem's social media pages, requiring

[1] U.S. FOOD AND DRUG ADMINISTRATION, Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization at 11, Jan. 2, 2020.

that individuals appearing in Fontem advertising be and appear to be over the age of 25, and restricting advertising to platforms where the Company can verify that the target audience is over the age of 21. Fontem will continue to monitor the demographic trends with respect to its flavored disposable products and take additional actions as necessary.

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?**

   As Mr. Blonde testified during the Subcommittee's February 5, 2020 hearing, Fontem is complying with the FDA Guidance. Given that the FDA Guidance only recently came into effect, it is difficult to state with certainty its effects to date. However, Fontem remains committed to working with FDA on youth access prevention issues and will continue to maintain a robust youth access prevention program.

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?**

   Fontem has had a productive working relationship with FDA and will continue to work with FDA to ensure that its products are kept out of the hands of youth. In its engagement with FDA on youth access prevention issues, the Company has not experienced any difficulties attributable to a lack of resources at FDA.

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?**

   As discussed at the hearing, some ENDS products manufacturers have publicly announced their intention to make PMTA filings public for certain products, thus providing this information to these entities.

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?**

We do not believe any formal regulatory or legislative changes are necessary at this point. However, we do believe additional clarification should be provided by FDA to retailers regarding potential liability for continuing to sell "violative" products after May 12, 2020. Historically, FDA has limited enforcement of the premarket review provisions of the Tobacco Control Act to the entities responsible for making the premarket submissions: manufacturers. As a result, if a retailer carried products in violation of the FDA Guidance, FDA's enforcement would be directed to the manufacturer, the party responsible for introducing the product into commerce. However, on March 10, 2020, FDA published a number of Warning Letters, including a number sent to retailers for offering to sell tobacco products that had not obtained premarket review (in these cases, flavored ENDS products subject to the FDA Guidance). This represented a significant departure from past practice and has caused a number of concerns among retail stakeholders regarding direct liability for carrying products for which it has no premarket review authority, and no clear means to conclusively determine whether it is "legal" in the eyes of FDA and under the FDA Guidance. FDA should clarify the legal basis for enforcing directly against retailers in this context, and articulate the means by which the Agency expects retailers to verify the compliance status of tobacco products before presenting them for sale.

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**

Fontem has cooperated extensively with FDA in an attempt to proactively reduce youth access to ENDS products. The Company previously provided the Committee with all correspondence with FDA, including presentations to FDA, as Exhibits C through H of its September 20, 2019 Response to the Committee.

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?**

Fontem actively monitors the marketplace for counterfeit blu products and to date has not identified this as a significant issue. However, Fontem will continue to conduct robust monitoring of the marketplace and is prepared to engage with law enforcement as necessary.

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

   Fontem is committed to responsible product stewardship practices, which are reflected in the design, manufacture, and marketing of its products. In addition, Fontem engages in extensive research to understand its products and any potential associated risks. For additional specifics, please see the efforts detailed in Exhibit B to Fontem's December 20, 2019 Response to the Committee.