Juul Labs®

Jose Luis Murillo
Chief Regulatory Officer

October 30, 2023
By Email

Brian King, Ph.D., M.P.H.
Director, Center for Tobacco Products
Food and Drug Administration
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: September 25, 2023, Letter Regarding Referral to TPSAC of JUUL Labs, Inc.'s July 2023 PMTA

Dear Dr. King:

On behalf of JUUL Labs, Inc. (JLI or the Company), I write regarding the Letter[1] sent by several tobacco control organizations[2] on September 25, 2023, urging the Agency to "refer to the Tobacco Products Scientific Advisory Committee (TPSAC) the Premarket Tobacco Product Application (PMTA) recently filed by JLI for its 'next generation platform.'"[3]

JLI would welcome an FDA referral of JLI's PMTA (PM0007393) to the TPSAC. Our PMTA is comprised of a number of scientific studies and data supporting a finding that marketing the next generation platform would be appropriate for the protection of the public health. We believe proceedings before TPSAC could enhance transparency and support a holistic review of this science and evidence, including data supporting the proposed technologies to restrict underage access. As such, we stand ready to receive your instructions should you wish to place the application on an upcoming TPSAC docket.

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[1] See https://www.lung.org/getmedia/4e410839-8d0c-4b70-ac1b-3750d3646ec6/Letter-to-FDA-re-JUUL2-PMTA-9-25-23.pdf, accessed on September 29, 2023.

[2] Letter signatories include: American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Parents Against Vaping e-cigarettes (PAVe), and Truth Initiative.

[3] On July 18, 2023, JLI submitted PMTAs for the JUUL2 System (JUUL2 Device and Virginia Tobacco JUUL2 pods containing 18 mg/mL of nicotine). The submission tracking number (STN) for the application is: PM0007393. For the sake of clarity, throughout our July 2023 PMTA, including in the labeling and marketing materials, JLI refers to its next generation product as "JUUL2." JLI, however, is evaluating alternative commercial names for marketing in the U.S. Once JLI determines what the intended commercial name will be for the U.S., it will notify FDA and provide relevant information. For the purposes of this letter, we refer to the July 2023 PMTA as our "next generation product."

In the meantime, we would like to clarify certain misunderstandings contained in the September 25 Letter:

1. **The Letter Does Not Accurately Contextualize Low Underage Use of JUUL**

While youth use of e-cigarettes, including JUUL products, is unacceptable, the Letter mischaracterizes JUUL as "among the most popular e-cigarette brands among youth," in 2022. In reality, from 2019 to 2022, underage use of JUUL declined 95%, exceeding the 53% decline in overall underage ENDS use. Data from the National Youth Tobacco Survey (NYTS) demonstrates that use of JUUL as "usual brand" among past 30-day underage vapor product users fell from 57.9% in 2019,[4][4] to 6.8% in 2021,[5] and in 2022, JUUL was not even on the list of most often reported usual brands among middle school and high school students.[6] For use of JUUL as "usual brand" among past 30-day vapor product users, the report states "Data were statistically unreliable," likely due to low endorsement of JUUL as usual brand.

The Letter ignores the progress JLI has made since we initiated a company-wide reset in 2019.[7] To address issues from the past, we have implemented comprehensive steps to better align our policies and practices with the expectations of our stakeholders and to combat underage usage of JUUL products. A 95% reduction in youth usage of JUUL products between 2019 and 2022 represents significant progress – and JLI remains focused on restricting access to our products and limiting our products' appeal.

2. **The Letter Makes False Allegations About JLI's App**

The Letter correctly states that JLI's next generation platform is Bluetooth-enabled and capable of connecting to a mobile and web-based app for the next generation platform. The app enables age-verification technology, including device-locking and real-time product information and usage insights for age-verified consumers with industry-leading data-privacy protections. However, the Letter later speculates that JLI intends to use the app to "ensure that each consumer's addiction is sustained," and that "innovative technology will no doubt be part of its appeal to young people."

As a threshold matter, access to the app in the US would be – as in other markets where the app is available – limited to legal-age adults who have passed through JLI's age and identity verification process. To use the app, users are required to log-in to an existing age-verified JUUL account or set up an account and undergo age verification. As part of the age-verification, users may be required to upload images of a government issued identity document, as well as a photograph, which are verified through a third-party

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[4] Cullen KA, Gentzke AS, Sawdey MD, et al. e-Cigarette Use Among Youth in the United States, 2019. JAMA. 2019;322(21):2095–2103. doi:10.1001/jama.2019.18387.
[5] Park-Lee E, Ren C, Sawdey MD, et al. Notes from the Field: E-Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1387–1389. DOI: http://dx.doi.org/10.15585/mmwr.mm7039a4.
[6] Cooper M, Park-Lee E, Ren C, Cornelius M, Jamal A, Cullen KA. Notes from the Field: E-cigarette Use Among Middle and High School Students — United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:1283–1285. DOI: http://dx.doi.org/10.15585/mmwr.mm7140a3.
[7] In the fall of 2019, new JLI executive leadership initiated a reset of the company to restructure our operations and refocus our priorities on the science and evidence in support of our products and to combat underage use through data-driven measures.

vendor. Any concerns with respect to the appeal of, or access to, the app for those underage are resolved by JLI's strict access prevention measures.

With respect to allegations that the app would "ensur[e] that each consumer's addiction is sustained," JLI is puzzled as to the basis for this allegation. As those at FDA charged with reviewing JLI's July 2023 PMTA will no doubt already know, the next generation platform contains no modifiable settings, meaning neither JLI nor the end user can modify device performance; e.g., increasing or decreasing aerosol delivery. Additionally, the app does not provide feedback to users based on data related to product usage – it simply provides information about how users are using their next generation platform.

JLI does not collect device usage or geolocation data. Next generation platform usage data, which are used to generate usage insights, are stored locally on the user's phone (mobile app). Users may enroll in automatic backup of data to ensure their insights will remain available if they lose or change their phone, or if they are using the web-enabled version of the app. Commercial versions of the app protect users' puff data with a combination of local-only storage and end-to-end encryption, so that only they can view it. JLI has no access to the content, including puff data or other usage insights.

There are two limited exceptions through which JLI may access usage data:

1) A user submits a warranty claim for a returned device. In this case, data may be accessed directly from the device if it is relevant to the assessment of a potential device performance issue; and
2) A user who has provided informed consent enrolls in a clinical, behavioral, or product improvement study. That puff data is de-identified and carefully protected via best practices for research studies.

Because JLI does not collect commercial product use data, cannot impact device operating parameters, does not have access to user-specific usage data, and does not communicate with consumers about their product use patterns, the concerns expressed in the Letter are unfounded.

Finally, and as discussed in detail in our July 2023 PMTA, multiple behavioral studies and lines of evidence demonstrate that the abuse liability of JLI's next generation platform is lower than combustible cigarettes and within the range of currently marketed pod-based tobacco-flavored ENDS products.

Rather than creating unique public health issues, the app is intended to help address them. In fact, JLI's technology, including the next generation platform's Bluetooth capability and app, is precisely the novel age-gating technology application FDA has said it will prioritize.[8] The app enables device-level access restrictions to further limit the potential for underage use. For example, the app enables users to voluntarily lock their JUUL2 Device, either on an ad hoc basis or at prescribed time intervals ("auto-lock"), reducing the risk of unauthorized access to the device (e.g., if the device is left unattended).

For non-tobacco flavors, in-line with FDA's statements regarding the need for device-level access controls to mitigate the risk of underage use,[9] the app provides a mechanism for more stringent device-level

[8] FDA Internal Memo obtained through FOIA process, "Office of Science (OS) Premarket Application Review Prioritization Plan" from Rosanna Beltre, Deputy Director, Division of Regulatory Project Management to Matthew Holman, Director, Office of Science, dated 08/31/2020.
[9] See, e.g., TPL Review of PMTAs: PM0000637.PD1 and PM0000713.PD1 at p. 36.

access controls. For example, JLI intends to submit, by year-end, a PMTA for a menthol next generation platform pod for use with the next generation platform device from JLI's July 2023 PMTAs.[10] Upon inserting a menthol-flavored pod, the next generation platform would automatically lock – i.e., it would not produce aerosol. A user would be required to connect the device to the app and either log in to an existing age-verified JUUL account or setup an account and undergo age verification in order to unlock the device and use the menthol flavored pod.

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We would be pleased to present our PMTA and underlying technology, science, and evidence supporting our next generation platform at a forthcoming TPSAC meeting and welcome the opportunity to discuss any questions you may have.

Sincerely,

[10] PM0007393.