Juul Labs®

Jose Luis Murillo
Chief Regulatory Officer

November 17, 2020

By Email

The Honorable Raja Krishnamoorthi
Chairman, Subcommittee on Economic and Consumer Policy
Committee on Oversight and Reform
United States House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515

Re: Response to November 13, 2020 Letter

Dear Chairman Krishnamoorthi:

On behalf of Juul Labs, Inc. (JLI or the Company), I am writing in response to your letter of November 13, 2020.

We are pleased to use this opportunity to offer our company's perspective on the data from the 2020 National Youth Tobacco Survey (NYTS) published by the Centers for Disease Control and Prevention (CDC) this past September, and to discuss our Premarket Tobacco Product Applications (PMTAs) currently pending before the Food and Drug Administration (FDA or the Agency). As always, we are committed to working cooperatively with the Subcommittee on Economic and Consumer Policy.

Our mission remains to transition the world's billion adult smokers away from combustible cigarettes, eliminate their use, and combat underage usage of our products. This mission remains as critical as ever, especially given that approximately 34 million Americans continue to use combustible cigarettes, leading to more than 480,000 premature deaths in the U.S. each year.

In furtherance of our mission, over the past year we have undertaken far-reaching actions to reset our company and category, and earn trust with our key stakeholders, including our regulators and policymakers. That effort included our decision, referenced in your letter, to voluntarily cease distribution of our flavored products other than tobacco and menthol. Indeed, we opted to pursue PMTAs for only tobacco and menthol flavors, consistent with our decision and informed by regulatory insights and data.

In addition, we halted all mass market product advertising and reorganized our entire company toward our scientific research efforts, product development for adult smokers, and combating underage usage. We also have been staunch supporters of Tobacco 21 legislation as an intervention to restrict underage access and will continue to work with states toward full implementation and enforcement of Tobacco 21.

While enormous work remains, recent data suggest that meaningful progress is being made on both aspects of our mission.

Our company estimates that as of today, approximately two million American adults have transitioned away from combustible cigarettes with the JUUL System. By this we mean that adult smokers — including many who were heavy smokers for 5 years or more — no longer use combustible cigarettes and, instead, have completely switched to a noncombustible alternative.

In addition, studies show that more than half of adult smokers who try JUUL products completely switch from combustible cigarettes within 6 months.[1] These data demonstrate the potential of our products to help significantly drive down smoking rates in the U.S. at a time when the use of combustible cigarettes remains, by far, the leading cause of preventable death in our country.

Regarding underage-use prevention, we were encouraged that the 2020 NYTS found that past 30-day use of electronic nicotine delivery systems (ENDS) among high school students decreased 29% from the previous year, while past 30-day use among middle school students decreased 55%.

This significant decline shows the potential for evidence-based interventions that restrict access to and limit appeal of ENDS products to address underage use. Such measures include raising the minimum-purchasing age for all tobacco products, including ENDS, to 21 years; increased efforts to drive retailer compliance with age-verification requirements; and FDA's January 2020 guidance, removing enforcement discretion for cartridge-based ENDS products in flavors other than tobacco and menthol and focusing enforcement on any ENDS product that is targeted to youth. Relatedly, active enforcement against illegally marketed and illicit, black-market products must remain a priority as demonstrated by our engagement with law enforcement and other stakeholders throughout the U.S. and around the world.

Though the data in this year's NYTS show encouraging progress, a troubling data point emerged with regard to disposable ENDS products. As FDA's Center for Tobacco Products (CTP) recently noted, the rate of use of disposable products rose from 2.4% in 2019 to 26.5% in 2020, representing an alarming uptick. The 2020 NYTS also revealed that, while FDA guidance has made unlawful the sale or distribution of cartridge-based ENDS products in flavors other than tobacco and menthol without marketing authorization, 80% of high schoolers who report using any ENDS product say they are using flavors. In fact, the top two most popular flavors were fruit and mint, neither of which have been distributed by JLI since November 2019. The implication is that many high school and middle school students

[1] Russell, C., Haseen, F. & McKeganey, N. Factors associated with past 30-day abstinence from cigarette smoking in adult established smokers who used a JUUL vaporizer for 6 months. Harm Reduct J 16, 59 (2019). https://doi.org/10.1186/s12954-019-0331-5

are using disposable ENDS products that are being marketed illegally and flouting FDA policy.

Given these data, CTP has stated that it will prioritize enforcement against flavored disposable ENDS products, which the Company does not market. Recent enforcement actions underscore the Agency's concern with the rise in underage use of disposable ENDS products as well as the use of menthol-flavored products that are marketed in a way that promote use by minors.[2] We are encouraged by the fact that since March, FDA has issued over 260 warning letters to manufacturers and online and brick-and-mortar retailers that sell unauthorized flavored ENDS products and since June has taken significant enforcement actions against illegal, unauthorized disposable products.

We support FDA's efforts to act against illegal products and, more broadly, we remain committed to working with all stakeholders to continue combating underage use through evidence-based interventions.

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It is against this backdrop that we wanted to address your specific inquiries.

With regard to menthol, it is our bedrock belief that FDA is the body best-positioned to develop and implement policy relating to tobacco products. As you know, the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), signed by former President Obama, was a years-long legislative process led by Congressman Henry Waxman and Senator Ted Kennedy, giving the Agency expansive authority and oversight over tobacco products.

FDA has exercised that authority, including by issuing its guidance related to flavored ENDS products in January 2020 which removed all non-tobacco, non-menthol flavored cartridge-based products until authorized through a PMTA. As it stated, the Agency's decision sought to strike the public health balance by maintaining ENDS products as a potential off-ramp for adults using combustible tobacco while ensuring these products do not provide an on-ramp to those underage. FDA did so after careful consideration of the data and made the decision to continue enforcement discretion as to both tobacco- and menthol-flavored ENDS products pending PMTA review. Indeed, since then, the Agency has reiterated its openness to considering PMTAs for flavored products and, according to public reports, there are thousands of PMTA applications pending for such products from our competitors.

FDA's careful balancing of combating underage use while promoting harm reduction for adult smokers is supported by ample market and scientific studies. Studies have shown that flavors are important to adult smokers considering alternatives to combustible cigarettes. For example, flavored products can help adult smokers switch and stay

[2] Press Release, "National Survey Shows Encouraging Decline in Overall Youth E-Cigarette Use, Concerning Uptick in Use of Disposable Products," FDA, 9/9/20

switched. But there is a crucial balance between effectively reaching adult smokers and restricting access and limiting appeal to those underage. This balance and approach are critical to the effort to reduce the harm caused by cigarettes, particularly at a time when the country has recently experienced a rebound of combustible cigarette sales.

In addition, twelve million U.S. adults currently smoke menthol cigarettes. We believe it is important for these adult smokers to have noncombustible alternatives available to them that mirror their smoking experience. Our data show that adult menthol cigarette smokers are more likely to transition away from combustible cigarettes with a menthol-flavored alternative.[3] Furthermore, in an environment in which Tobacco 21 is the law of the land and access controls are enforced, we believe menthol-flavored ENDS products should remain available for adult smokers. It would be a disservice to those adult smokers to deny them an alternative that they may prefer. Indeed, it would seem perverse to allow the continued sale of menthol cigarettes while banning menthol-flavored ENDS products. FDA has made it clear that it will continue to closely monitor underage use of menthol-flavored products, and we are committed to do the same.

We appreciate the Subcommittee's interest in understanding the science and evidence supporting our PMTAs. We would be happy to meet with you and your staff to discuss our applications.

Our company invested substantial resources to develop and submit the most rigorous PMTAs possible, conducting 110 scientific studies, including chemistry, toxicological, clinical, and behavioral research. Our submission seeks to make the case to FDA, based on science and evidence, that market authorization for the JUUL System is appropriate for the protection of public health and provides adult smokers a potentially less harmful alternative to combustible cigarettes, while including data-driven measures to combat underage use.

Our submission aligns with the PMTA process as required by the Tobacco Control Act and is informed by FDA guidance and other regulatory insights. Congress gave responsibility for premarket review and authorization of new tobacco products to FDA. And the Agency is guided by its public health mission and is well-positioned to provide the sort of science and evidence-based evaluation required to determine whether a product meets the standard of being appropriate for the protection of public health.

FDA's CTP employs more than 950 staff, with approximately 450 full time employees at the Office of Science, the group responsible for reviewing PMTA submissions. That Office is composed of experts from across disciplines including toxicologists, chemists, epidemiologists, clinicians and behavioral scientists. This experienced, expert, non-partisan

[3] Nicholas I. Goldenson, Shivaani Prakash, Gem M. Le, Joshua G. Vose, Erik M. Augustson. Effect of Mentholated Cigarette Smoking on Use of Flavored JL ENDS and Switching Behavior. Society for Research on Nicotine & Tobacco 2020 Annual Conference. March 14 2020.

team is well-positioned to evaluate our submission as well as those from other manufacturers on the basis of the scientific merits.

Furthermore, unlike the process for reviewing applications for modified risk tobacco products, the statutory process for reviewing PMTAs laid out in the Tobacco Control Act does not authorize public disclosure of the application. We, therefore, would respectfully submit that it would be inconsistent with the statute and FDA practice for us to provide our PMTAs to any government body other than FDA itself, as doing so could have the unintended effect of undermining the integrity and credibility of the scientific review that is critical to the PMTA process.

We are, however, committed to cooperating with the Subcommittee, as we have been doing since your initial inquiry in June 2019. Since that time, we have submitted more than 180,000 pages of material at your request. Moreover, we are committed to the transparent publication of our core scientific research. Thus far, we have published two peer-reviewed scientific studies, and plan to submit at least 12 more for publication by year's end.[4] We welcome public review of these papers and would be happy to share with the Subcommittee all of these papers in a timely fashion after they have gone through the peer-review process. Additionally, we have presented more than 30 posters of our research at scientific conferences around the globe and make these available on www.juullabsscience.com.

Finally, we stand ready to meet with you and Subcommittee staff to present in greater detail the science and evidence underlying our PMTA submission. We acknowledge the Subcommittee's interest in our applications and are happy to discuss these matters further while at the same time respecting and adhering to FDA's defined process for the review of PMTAs.

We remain fully committed to working cooperatively with this Subcommittee and appreciate your continued interest in these issues.

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[4] Nicholas I. Goldenson, August R. Buchhalter, Erik M. Augustson, Mark L. Rubinstein, Jack E. Henningfield. Abuse liability assessment of the JUUL system in four flavors relative to combustible cigarette, nicotine gum and a comparator electronic nicotine delivery system among adult smokers. Drug and Alcohol Dependence. November 2020. https://doi.org/10.1016/j.drugalcdep.2020.108395.

Joanna Jay, Erika L Pfaunmiller, Norman J Huang, Gal Cohen, Donald W Graff. Five-Day Changes in Biomarkers of Exposure Among Adult Smokers After Completely Switching From Combustible Cigarettes to a Nicotine-Salt Pod System. Nicotine & Tobacco Research, Volume 22, Issue 8. August 2020. https://doi.org/10.1093/ntr/ntz206.

Sincerely,

cc: The Honorable Carolyn Maloney, Chairwoman, Committee on Oversight and Reform

The Honorable James Comer, Ranking Member, Committee on Oversight and Reform

The Honorable Michael Cloud, Ranking Member, Subcommittee on Economic and Consumer Policy