FDA Warning Letter to JUUL

Dear Mr. Burns:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) reviewed testimony from the July 24-25, 2019 hearing on "Examining JUUL's Role in the Youth Nicotine Epidemic," of the Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform of the United States House of Representatives ("House Subcommittee"), documents from FDA's September 24-28, 2018 inspection of JUUL Labs, Inc.'s (JUUL) headquarters in San Francisco, California, JUUL's submissions to the Agency, and JUUL's website, https://www.juullabs.comExternal Link Disclaimer, and determined that JUUL products, which are electronic nicotine delivery system (ENDS) products, are manufactured, marketed, advertised, labeled, and offered for sale or distribution to customers in the United States. Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), as amended by the Family Smoking Prevention and Tobacco Control Act, these products are tobacco products because they are made or derived from tobacco and intended for human consumption. Certain tobacco products, including ENDS products (*e.g.,* e-cigarettes and e-liquids), are subject to FDA jurisdiction under section 901(b) of the FD&C Act (21 U.S.C. § 387a(b)).

Based on our review of the information described above, FDA has determined that JUUL adulterated its products under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)) by selling or distributing them as modified risk tobacco products without an FDA order in effect that permits such sale or distribution.

Modified Risk Tobacco Products Without an Appropriate FDA Order in Effect are Adulterated

Our review of testimony from the July 24-25, 2019 House Subcommittee hearing, documents from FDA's inspection of JUUL's headquarters, JUUL's submissions to the Agency, and JUUL's website, https://www.juullabs.comExternal Link Disclaimer, revealed that your firm has engaged in labeling, advertising, and/or other activities directed to consumers, in which JUUL explicitly and/or implicitly has represented that JUUL products are free of a substance, have a reduced level of or exposure to a substance, and/or that JUUL products present a lower risk of tobacco-related disease or are less harmful than one or more other commercially marketed tobacco products.

The July 24-25, 2019 House Subcommittee hearing included the following evidence:

1. A JUUL representative speaking with students at his presentation stated that JUUL "was much safer than cigarettes" and that "FDA would approve it any day."[1]
2. The JUUL representative speaking with students at his presentation called JUUL "totally safe."[2]
3. The JUUL representative speaking with students at his presentation stated that a student "...should mention JUUL to his [nicotine-addicted] friend...because that's a safer alternative than smoking cigarettes, and it would be better for the kid to use."[3]
4. The JUUL representative speaking with students at his presentation stated, "FDA was about to come out and say it [JUUL] was 99% safer than cigarettes...and that...would happen very soon...."[4]

Referring to your ENDS products as "99% safer" than cigarettes, "much safer" than cigarettes, "totally safe," and "a safer alternative than smoking cigarettes" is particularly concerning because these statements were made directly to children in

school. Our concern is amplified by the epidemic rate of increase in youth use of ENDS products, including JUUL's products, and evidence that ENDS products contribute to youth use of, and addiction to, nicotine, to which youth are especially vulnerable.[5]

In addition, your "Letter from the CEO" states: "[JUUL's] simple and convenient system incorporates temperature regulation to heat nicotine liquid and deliver smokers the satisfaction that they want without the combustion and the harm associated with it." On April 25, 2018, your letter appeared in an email that JUUL sent to a parent in response to her complaint that the firm sold JUUL products to her child. On May 8, 2018, your letter appeared on JUUL's website, https://www.juullabs.comExternal Link Disclaimer.[6] This letter provides further confirmation of the evidence from the hearing testimony that JUUL has marketed JUUL products as modified risk tobacco products.

A tobacco product is considered a "modified risk tobacco product," *inter alia*, if its label, labeling, or advertising explicitly or implicitly represents that: (1) the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products; (2) the product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or (3) the product or its smoke does not contain or is free of a substance (section 911(b)(2)(A)(i) of the FD&C Act (21 U.S.C. § 387k(b)(2)(A)(i))); or where the manufacturer has taken any action directed to consumers through media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances (section 911(b)(2)(A)(iii) of the FD&C Act (21 U.S.C. § 387k(b)(2)(A)(iii))).

Under section 911(a) of the FD&C Act (21 U.S.C. § 387k(a)), no person may introduce or deliver for introduction into interstate commerce any modified risk

tobacco product without an FDA order in effect under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)). A modified risk tobacco product application under section 911(d) of the FD&C Act (21 U.S.C. § 387k(d)) is required to provide scientific evidence and other information to support issuance of an order under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)). A product that is in violation of section 911(a) of the FD&C Act (21 U.S.C. § 387k(a)) is adulterated under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)).

JUUL has marketed its ENDS products as modified risk tobacco products because JUUL's labeling, advertising, and/or other actions directed to consumers (examples of which are referenced above), represent, or would be reasonably expected to result in consumers believing, that the products present a lower risk of tobacco-related disease or are less harmful than one or more other commercially marketed tobacco products; contain a reduced level of a substance or present a reduced exposure to a substance; and/or do not contain or are free of a substance or substances. JUUL adulterated its products under section 902(8) of the FD&C Act (21 U.S.C. § 387b(8)) by selling or distributing them as modified risk tobacco products without an appropriate FDA order in effect under section 911(g) of the FD&C Act (21 U.S.C. § 387k(g)) that permits such sale or distribution.

Conclusion

The violations discussed in this letter do not necessarily constitute an exhaustive list. To the extent you have not already done so, you should immediately correct the violations that are referenced above, as well as violations that are the same as or similar to those stated above, and take any necessary actions to bring your tobacco products into compliance with the FD&C Act. It is your responsibility to ensure that your tobacco products, all related labeling and advertising, and all other activities by JUUL directed to consumers, such as in any media in which you advertise and any retail establishments, comply with each applicable provision of the FD&C Act and FDA's implementing regulations. Failure to ensure compliance with the FD&C Act may result in FDA initiating further action, including, but not limited to, civil money

penalties, seizure, and/or injunction. Please note that any adulterated and misbranded tobacco products offered for import into the United States are subject to detention and refusal of admission.

Please submit a written response to this letter within 15 working days from the date of receipt describing your corrective actions, including the dates on which you discontinued the violative promotion, labeling, advertising, sale, and/or distribution of these tobacco products. In your written response, please also describe your plan for maintaining compliance with the FD&C Act, including your plan to prevent violations that are the same as or similar to those stated above, such as through, for example, new internal controls and training. You can find the FD&C Act through links on FDA's homepage at http://www.fda.gov. If you do not believe that your products are in violation of section 911 of the FD&C Act (21 U.S.C. § 387k), please provide us with your reasoning and provide any and all scientific evidence and data, if any, that support that your statements and representations do not explicitly or implicitly convey that JUUL products pose less risk, are less harmful, present reduced exposure, or are safer than other tobacco products.