CENTER FOR TOBACCO PRODUCTS

September 9, 2019

VIA UPS and Electronic Mail

Kevin Burns, CEO
JUUL Labs, Inc.
560 20th Street
San Francisco, CA 94107-4344
kburns@juul.com

Dear Mr. Burns:

I am writing to request documents and information from JUUL Labs, Inc. (JUUL) regarding JUUL's marketing, advertising, promotional, and education campaigns, as well as certain product development activity. As we have previously communicated to you and your firm, the Food and Drug Administration (FDA) is deeply concerned by the epidemic rate of increase in youth use of electronic nicotine delivery system (ENDS) products as well as the uncertainty regarding their immediate and long-term effects on the public health. Despite commitments JUUL has made to address this epidemic, JUUL products continue to represent a significant proportion of the overall use of ENDS products by children. We believe you have a continuing responsibility to take action to address the epidemic of youth use of your products, some of which appears to have been a direct result of your product design and marketing campaigns, whether or not some of these practices have been discontinued.

We were particularly troubled by recent testimony provided to the Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform of the United States House of Representatives ("Subcommittee") during a hearing entitled, "Examining JUUL's Role in the Youth Nicotine Epidemic" on July 24-25, 2019. As detailed further below, that testimony revealed JUUL engaged in a wide variety of promotional activities and outreach efforts to persuade potential customers, including youth, to use JUUL products. Witnesses testified, for example, that JUUL advertising saturated social media channels frequented by underage teens and that JUUL used influencers and discount coupons to attract new customers.

We are also concerned that parts of the "Make the Switch" campaign may also convey that switching to JUUL is a safer alternative to cigarettes, in that using JUUL products poses less risk or is less harmful than cigarettes. Further, FDA believes that the hearing testimony regarding JUUL's "Switching Program" presentation to the Cheyenne River Sioux Tribe Health Committee may help inform the message that JUUL intends to convey in the "Make the Switch" campaign.

We were further troubled by testimony concerning JUUL's use of nicotine-salt e-liquids in its products and the concentration of nicotine in its products, which potentially could increase the addictiveness of the products.

This letter describes statements and activities about which we are requesting documents and information. We also have questions related to JUUL's product design. Furthermore, it appears to us that, despite previous document requests from FDA that were substantially similar to ones from the Subcommittee, see the section below on Previous Document Requests, you submitted more documents to the Subcommittee than to FDA. Accordingly, we are requesting that you provide us with documents related not only to the specific examples listed below, but also to the broader promotional activities and outreach efforts that the examples illustrate. We also request that you provide us with documents that you have provided and/or will provide to Congress, as outlined below.

July 24-25, 2019 Hearing: "Examining JUUL's Role in the Youth Nicotine Epidemic"

The Subcommittee hearing revealed the following issues:

Educational Engagement and Outreach

1. Ms. Meredith Berkman, Co-founder, Parents Against Vaping e-cigarettes (PAVe), testified that, "In California, a retired school superintendent was offering schools in his state and in Massachusetts money if they would implement the anti-JUUL curriculum that…a man named Bruce Harder was offering on JUUL's behalf."[1]

2. On July 24, 2019, Dr. Robert Jackler, M.D., Professor at Stanford University School of Medicine, testified that, "Altria may provide services to JUUL with respect to…youth vaping prevention…."[2]

3. On July 25, 2019, in response to questions from Chairman Krishnamoorthi about JUUL's program to pay schools $10,000 or more to use a JUUL youth prevention curriculum, Ms. Ashley Gould, Chief Administrative Officer, JUUL Labs, Inc., testified: "That is not currently the case. We ended that program in the fall of 2018," and that, "…there were six schools that received funding from JUUL to implement programming to prevent teen vaping…."[3]

4. In addition, in response to questions from Chairman Krishnamoorthi about internal JUUL correspondence in 2018 about setting up a booth at a school health fair, Ms. Gould testified that JUUL ended its youth prevention program.[4]

[1] Hearing, July 24, 2019, Testimony of Ms. Meredith Berkman, at minutes 53:58 – 54:13 (https://youtu.be/m3iEMrAd83o).
[2] Dr. Robert Jackler, M.D., Stanford University School of Medicine. The Role of the Company in the JUUL Teen Epidemic, Testimony for the House Subcommittee on Economic and Consumer Policy, at p. 12 (July 24, 2019).
[3] Hearing, July 25, 2019, Testimony of Ms. Ashley Gould, Chief Administrative Officer, JUUL Labs, Inc., at minutes 3:07:50 – 3:08:08, 3:08:45 – 3:09:10 (https://www.youtube.com/watch?v=xetCY0jEPAs&feature=youtu.be).
[4] Hearing, July 25, 2019, Testimony of Ms. Ashley Gould, Chief Administrative Officer, JUUL Labs, Inc., at minutes 3:09:28 – 3:10:50 (https://www.youtube.com/watch?v=xetCY0jEPAs&feature=youtu.be).

5. In response to questions about JUUL's agreement to pay the Richmond, California Police Activities League (RPAL) $89,000 to use its youth prevention curriculum in the RPAL youth program, which is for 12- to 17-year-olds who face suspension from school for using e-cigarettes, Ms. Gould testified that JUUL ended its youth prevention program.[5]

6. Further, in response to questions about JUUL providing grants to youth programs, such as a $134,000 grant for a summer program at a charter school in Baltimore, Maryland, for 80 students in grades 3 – 12, and for which the school agreed to provide JUUL with the students' data (e.g., surveys, journals, activity logs), Ms. Gould testified that she, "…would have to check the contracts, but whatever grants were made were focused on youth prevention efforts."[6]

7. Moreover, in response to questions about JUUL's agreement with Life Skills, Inc., to partner with church groups to provide health education to a thousand youth in Baltimore, even though internal JUUL correspondence indicated the company was aware that tobacco companies promoted such initiatives in the 1990s, Ms. Gould again testified that JUUL ended its youth prevention program.[7]

8. In addition, in response to questions about JUUL's contract with a consulting group to promote cessation programs run by community-based groups, including veterans' organizations, Ms. Gould testified that she would need to review the documents being referenced.[8]

FDA requests that you provide the Agency all documents and information that relate to:

- The statements, representations, and events referenced above;

- JUUL's actual or considered engagement with, outreach to, and curricula for other youth-oriented, faith-based or community-based institutions, organizations, and programs (*e.g.*, schools, churches, camps, extracurricular programs); and

- JUUL's actual or considered engagement with, outreach to, and curricula for youth and adults associated with such institutions, organizations, and programs (e.g., individual students, parents, teachers, participants, administrators, staff).

Please include any instructions, training materials, and any other materials (e.g., guidance, talking points) provided to those conducting such engagement and outreach (e.g., presentations, programs) and any materials used or distributed during such engagement and outreach. Please also include any and all documents and information related to the actual or considered termination of such engagement and outreach.

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[5] Hearing, July 25, 2019, Testimony of Ms. Ashley Gould, Chief Administrative Officer, JUUL Labs, Inc., at minutes 3:18:22 – 3:19:15 (https://www.youtube.com/watch?v=xetCY0jEPAs&feature=youtu.be).
[6] Hearing, July 25, 2019, Testimony of Ms. Ashley Gould, Chief Administrative Officer, JUUL Labs, Inc., at minutes 3:19:20 – 3:20:49 (https://www.youtube.com/watch?v=xetCY0jEPAs&feature=youtu.be).
[7] Hearing, July 25, 2019, Testimony of Ms. Ashley Gould, Chief Administrative Officer, JUUL Labs, Inc., at minutes 3:20:50 – 3:21:36 (https://www.youtube.com/watch?v=xetCY0jEPAs&feature=youtu.be).
[8] Hearing, July 25, 2019, Testimony of Ms. Ashley Gould, Chief Administrative Officer, JUUL Labs, Inc., at minutes 3:22:20 – 3:23:40 (https://www.youtube.com/watch?v=xetCY0jEPAs&feature=youtu.be).

Tribal Engagement and Outreach

9. On July 24, 2019, Ms. Rae O'Leary, RN, MPH, Public Health Analyst, Missouri Breaks Industries Research, Inc., representing the Cheyenne River Sioux Tribe (CRST) Health Committee, testified: "On January 23, 2019, representatives from JUUL Labs, Inc., traveled to Eagle Butte, SD, to offer to the CRST Tribal Council, in a specially-called session, a "Switching Program," as well as free starter kits to the CRST Tribe's Chairman, and all Tribal Council members present…."[9] On this point, Ms. O'Leary noted that JUUL representatives provided "free product to our decision makers…."[10] Ms. O'Leary further testified: "On February 1, 2019, I was notified that three representatives from JUUL had traveled back to Eagle Butte, SD to present a "Switching Program" to the CRST Health Committee...."[11] Ms. O'Leary then testified that the JUUL representatives presenting this program "…introduced themselves as public health professionals…," and that, "[i]n this presentation (slides in Attachment C), JUUL made claims that their product is effective for smoking cessation and less harmful than combustible tobacco products….".[12]

10. Ms. O'Leary testified further regarding the presentation, stating that it included the following statements and representations:

    a. "JUUL Labs, Inc. Mission, Department Mission, Partnering with Tribes to Improve Lives."[13]

    b. "The Costs of Smoking Are Huge…For every 1% of cigarette smokers who switch to vapor, lifetime costs savings to Medicaid programs would be $2.9 million…It's time for an alternative to cigarettes…."[14]

    c. "Elimination of combustible cigarettes is crucial to reduce risk of harm"[15]

    d. "Improve the lives of the world's one billion adult smokers"[16]

    e. "Best-in-class temperature control designed to reduce harmful combustion byproducts…."[17]

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[9] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 1 (July 24, 2019).
[10] Hearing, July 24, 2019, Testimony of Ms. Rae O'Leary, RN, MPH, at minutes 2:08:25 – 2:08:35 (https://youtu.be/m3iEMrAd83o).
[11] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 1 (July 24, 2019).
[12] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at Attachment C (July 24, 2019) (Exhibit A). See also, Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 2 (July 24, 2019).
[13] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 2 and Attachment C, Slide 4 (July 24, 2019).
[14] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 2 and Attachment C, Slide 5 (July 24, 2019).
[15] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 2 and Attachment C, Slide 6 (July 24, 2019).
[16] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 2 and Attachment C, Slide 8 (July 24, 2019).
[17] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, Attachment C, Slide 16 (July 24, 2019).

f. "Combustion yields toxic byproducts linked to cancer, heart disease, COPD and respiratory diseases…Switching completely from cigarettes to non-combustible tobacco products reduces exposure to many of these toxic byproducts, in some cases up to 99% or to levels that are not detectable…Cigarette toxins…Over 7,000 chemicals…69 known carcinogenic compounds…400 other toxins: tar, carbon monoxide, formaldehyde, ammonia, hydrogen cyanide, arsenic, lead and DDT…."[18]

g. "Pilot Switching Program," "Have smokers that can't quit? JUUL has created a program where you can help them switch…with minimal cost to you…."[19] Regarding this statement, Ms. O'Leary testified that, "…using words like quit, switch, cessation is implied and that was the impression of the council tribal members who were on the other end of this presentation…."[20]

h. "JUUL has enabled millions of adult smokers to replace cigarettes. Our way to helping 20 million make the switch by 2020."[21]

11. In addition, Ms. O'Leary testified: "The JUUL presenters, who claimed a 'public health approach'…proposed that healthcare professionals from CRST's Tribal Health Department refer smokers that are 21 years or older to their 'Switching Program.' Using their referral, patients would enroll in JUUL's online portal, in which the patient would enter personal data about themselves and their tobacco/nicotine behaviors. JUUL would sell starter kits (valued at $50) to the Tribe for $5. The Tribe would then provide starter kits to patients who enroll in the 'Switching Program' for free. The presenters stated…that 'the value of their initial investment to build the online portal is $260,000, and per month it's actually a continuation of over $30,000.' Later, after the recording ended, JUUL representatives indicated that their investment was worth over $600,000."[22]

12. Moreover, Ms. O'Leary testified that, "When asked about youth use of JUUL, one presenter replied, 'we have never purposely marketed to children,' and then diverted to reduced harm stating, 'If you take [a] look at the larger bucket of literature, there are clear studies that document reduced harm by switching from combustible products to e-cigarettes'…."[23]

13. Ms. O'Leary also testified that, "As a result of my advocacy against Tribes partnering with Tobacco or E-Cigarette Companies, I have learned that JUUL has approached at least two other Tribes, and two national American Indian organizations, the National Congress of American Indians and the National Indian Health Board."[24]

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[18] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, Attachment C, Slide 17 (July 24, 2019).
[19] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 3 and Attachment C, Slides 20-21 (July 24, 2019).
[20] Hearing, July 24, 2019, Testimony of Ms. Rae O'Leary, RN, MPH, at minutes 1:46:10 – 1:46:33 (https://youtu.be/m3iEMrAd83o).
[21] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, Attachment C, Slide 22 (July 24, 2019).
[22] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 3 (July 24, 2019).
[23] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 3 (July 24, 2019).
[24] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 3 (July 24, 2019).

FDA requests that you provide the Agency all documents and information that relate to JUUL's actual or considered engagement with, outreach to, and curricula for Tribes; Tribal organizations, institutions, and programs; and Tribal members. Please include any instructions, training materials, and any other materials (e.g., guidance, talking points) provided to those conducting such engagement and outreach (e.g., presentations, programs) and any materials used or distributed during such engagement and outreach. Please also include any and all documents and information related to the actual or considered termination of such engagement and outreach.

Health Insurer and Employer Engagement and Outreach

At the hearing, JUUL was questioned about company efforts to market JUUL to companies and insurers to help their employees stop smoking and supposedly lower health care costs and apparently hired a former health care executive to run that team. FDA requests that you provide the Agency all documents and information that relate to JUUL's actual or considered engagement with, and outreach to: health insurers; employers; health care providers; insurer, employer, and provider institutions, organizations, and programs; and insureds and employees. Please include any instructions, training materials, and any other materials (e.g., guidance, talking points) provided to those conducting such engagement and outreach (e.g., presentations, programs) and any materials used or distributed during such engagement and outreach. Please also include any and all documents and information related to the actual or considered termination of such engagement and outreach.

Additional Marketing Practices and Research Activities

14. On July 24, 2019, Dr. Robert Jackler, M.D., Professor at Stanford University School of Medicine, testified that, "JUUL's early marketing (2015-early 2016) was patently youth oriented. For the next 2 ½ years its advertising saturated social media channels frequented by underage teens."[25]

15. Dr. Jackler further testified that, "Discount coupons offered cheap devices, a smart move as most profit is via repeat purchases of their nicotine pods. Seeking to recruit users to act as one of their marketing team members they [JUUL] offered "refer a friend and get a discount."[26] Moreover, Dr. Jackler testified that, "To ramp up its social media promotion JUUL used Influencers [and] affiliates… JUUL's affiliate program recruited those who authored favorable reviews of its products. Via a customized 'buy now' link, JUUL kicked back 20% of purchase price as a reward to favorable reviewers."[27] In addition, Dr. Jackler testified that after minors unsuccessfully tried to purchase JUUL products from JUUL's website, "…within a day each received a follow up e-mail notice that read 'Welcome to JUUL.' Shortly thereafter they received a series of advertising emails from JUUL including a discount coupon to buy a starter kit. After notifying senior leaders of JUUL of this practice, they promptly discontinued it."[28]

[25] Dr. Robert Jackler, M.D., Stanford University School of Medicine. The Role of the Company in the JUUL Teen Epidemic, Testimony for the House Subcommittee on Economic and Consumer Policy, at p. 2 (July 24, 2019).
[26] Dr. Robert Jackler, M.D., Stanford University School of Medicine. The Role of the Company in the JUUL Teen Epidemic, Testimony for the House Subcommittee on Economic and Consumer Policy, at p. 9 (July 24, 2019).
[27] Dr. Robert Jackler, M.D., Stanford University School of Medicine. The Role of the Company in the JUUL Teen Epidemic, Testimony for the House Subcommittee on Economic and Consumer Policy, at p. 9-10 (July 24, 2019).
[28] Dr. Robert Jackler, M.D., Stanford University School of Medicine. The Role of the Company in the JUUL Teen Epidemic, Testimony for the House Subcommittee on Economic and Consumer Policy, at p. 43-44 (July 24, 2019).

16. On July 25, 2019, during the testimony of Mr. James Monsees, Co-Founder and Chief Product Officer of JUUL, regarding questions about JUUL documents from March 2015 – May 2018 regarding JUUL's use of influencers and influencer programs, Mr. Monsees stated that he would provide a written response.[29]

17. On July 24, 2019, Dr. Jackler also testified that, "JUUL has commissioned many studies, conducted by private research institutes rather than independent university or governmental scientists. JUUL uses a research group whose primary activity has been to perform contract research for major tobacco companies…."[30] In addition, Dr. Jackler testified that, "JUUL has been reaching out to numerous universities offering to fund JUUL related research…JUUL would manage the grant selection process – a practice which insures commercial bias."[31]

FDA requests that you provide the Agency all documents and information that relate to:

- The statements, representations, and events referenced above;
- JUUL's actual or considered referral, affiliate, and influencer programs;
- JUUL's actual or considered use of any data about youth, such as any data collected from youth, for marketing or other purposes (*e.g.*, data collected by educational institutions about their students);
- JUUL's actual or considered use of discounting, coupons, rebates, or other price promotion tools; and
- JUUL's actual or considered commissioning of, and selecting grants for, studies and research.

"Make the Switch" Campaign and "Switching Program" Presentation

As detailed in a Warning Letter that FDA is issuing today, JUUL has marketed its products as modified risk tobacco products, without an appropriate FDA order in effect under section 911(g) of the Federal Food, Drug, and Cosmetic (FD&C) Act, in violation of section 911(a) of the FD&C Act. The Warning Letter noted that JUUL has referred to its products, for example, as "99% safer" than cigarettes, "much safer" than cigarettes, "totally safe," and "a safer alternative than smoking cigarettes." In addition, we are concerned that parts of the "Make the Switch" campaign and the "Switching Program" presentation to the Cheyenne River Sioux Tribe may also convey that switching to JUUL is a safer alternative to cigarettes, in that using JUUL products poses less risk or is less harmful than cigarettes.

[29] Hearing, July 25, 2019, Testimony of Mr. James Monsees, Co-Founder and Chief Product Officer of JUUL, at minutes 1:44:30 – 1:50:00 (https://www.youtube.com/watch?v=xetCY0jEPAs&feature=youtu.be).
[30] Dr. Robert Jackler, M.D., Stanford University School of Medicine. The Role of the Company in the JUUL Teen Epidemic, Testimony for the House Subcommittee on Economic and Consumer Policy, at p. 18 (July 24, 2019).
[31] Dr. Robert Jackler, M.D., Stanford University School of Medicine. The Role of the Company in the JUUL Teen Epidemic, Testimony for the House Subcommittee on Economic and Consumer Policy, at p. 19 (July 24, 2019).

JUUL's "Make the Switch" campaign consists of several advertisements, with the tag line, "Make the switch."[32] For example, these advertisements feature statements and representations such as:[33]

1. "Smoking," followed by, "Quit. Start smoking again," stated 30 times, followed by, "Switch," and "The average smoker tries to quit 30 times. Make the switch."

2. "34 million Americans still smoke cigarettes. Make the Switch."

3. "More than one million smokers have joined the community. Make the switch."

4. "'[JUUL is] a smart, really well thought-out alternative to smoking.' Make the switch."

5. "'I was looking to find something to replace cigarettes. The switch was easy.' Make the switch."

6. "This is the year. Make the switch."

7. "Sage smoked for 23 years, and switched to JUUL in 2018. 'I hadn't planned to switch. But after a week of having the JUUL in my hand, I started reaching for it over my pack of cigarettes.' Make the Switch."

8. "Reuben and Malissa smoked for 30 years, and switched to JUUL in 2018. 'I've been a smoker a long, long time, but the transition has really been positive. I'm pleased we've done it together.' Make the switch."

Additional JUUL advertisements include statements and representations, such as:[34]

9. "I think [JUUL is] an amazing invention…I don't know how we lived without that. The alternative for adult smokers."

10. "JUUL Labs is on a mission to improve the lives of the world's one billion adult smokers by eliminating cigarettes."

Further, the hearing testimony includes several other statements and representations, in the JUUL representatives' "Switching Program" presentation to the Cheyenne River Sioux Tribe Health Committee:

11. "Elimination of combustible cigarettes is crucial to reduce risk of harm"[35]

12. "Improve the lives of the world's one billion adult smokers"[36]

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[32] See, e.g., JUUL "Make the Switch" advertisements and additional JUUL advertisements (Exhibits B – K) and May 9, 2019 letter from American Academy of Pediatrics, et al. to Norman E. Sharpless, M.D., Acting Commissioner of Food and Drugs (Exhibit L).
[33] JUUL "Make the Switch" advertisements (Exhibits B – I).
[34] See, additional JUUL advertisements (Exhibits J and K).
[35] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 2 and Attachment C, Slide 6 (July 24, 2019).
[36] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, at p. 2 and Attachment C, Slide 8 (July 24, 2019).

13. "Best-in-class temperature control designed to reduce harmful combustion byproducts…."[37]

14. "Combustion yields toxic byproducts linked to cancer, heart disease, COPD and respiratory diseases…Switching completely from cigarettes to non-combustible tobacco products reduces exposure to many of these toxic byproducts, in some cases up to 99% or to levels that are not detectable…Cigarette toxins…Over 7,000 chemicals…69 known carcinogenic compounds…400 other toxins: tar, carbon monoxide, formaldehyde, ammonia, hydrogen cyanide, arsenic, lead and DDT…."[38]

FDA requests that you provide the Agency all documents and information that relate to the statements, representations, and events referenced above. In addition, we request that you provide any and all scientific evidence and data, including consumer perception studies, if any, related to whether or not each statement and representation explicitly or implicitly conveys that JUUL products pose less risk, are less harmful, present reduced exposure, or are safer than other tobacco products. We also request that you provide any and all scientific evidence and data, including consumer perception studies, if any, related to whether or not each statement and representation explicitly or implicitly conveys that JUUL products are smoking cessation products.

Nicotine Salts

During the hearing, testimony also focused on JUUL's use of nicotine-salt e-liquids in its products and the concentration of nicotine in its products. For instance, on July 24, 2019, Dr. Robert Jackler of Stanford University testified that, "JUUL introduced salt nicotine, a chemical formulation which reduces the bitterness of nicotine, enabling an average of 3x higher concentration than its predecessors," and that, "JUUL trigger[ed] a nicotine arms race among its copycats, with all utilizing highly concentrated salt nicotine (≥5%)."[39] On July 25, 2019, in questioning Mr. James Monsees, Co-Founder and Chief Product Officer of JUUL, Representative Wasserman Schultz stated that when JUUL entered the market, it "…used a nicotine salt formula that removed the harshness and bad taste and then tripled the nicotine content over existing products, making JUUL the most potent e-cigarette on the market…."[40]

FDA requests that you provide the Agency all documents and information that relate to the following:

- Aerosol particle size analysis of aerosol formed from your device and e-liquid, including from research that compares aerosol particle size data to data on aerosol particle size analysis from combusted cigarettes;

- Experimental design and data on pK studies from your device, your e-liquid, and combusted cigarettes;

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[37] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, Attachment C, Slide 16 (July 24, 2019).
[38] Ms. Rae O'Leary, RN, MPH. Testimony before the Subcommittee on Economic and Consumer Policy, Attachment C, Slide 17 (July 24, 2019).
[39] Dr. Robert Jackler, M.D., Stanford University School of Medicine. The Role of the Company in the JUUL Teen Epidemic, Testimony for the House Subcommittee on Economic and Consumer Policy, at p. 17 (July 24, 2019).
[40] Hearing, July 25, 2019, Statements of Representative Wasserman Schultz, at minutes 2:08:50 – 2:09:01 (https://www.youtube.com/watch?v=xetCY0jEPAs&feature=youtu.be).

- How the design and performance of your device and/or e-liquid, including the level, formulation, and delivery specifications of nicotine, affect lung deposition as related to the use and addictive potential of the product;

- Comparisons of electronic nicotine delivery systems (ENDS) with nicotine salt e-liquid, ENDS with free nicotine e-liquid, and combusted cigarettes, including, for example, with regard to consumer perception and use; and

- JUUL's use of nicotine salt e-liquids in its products.

In addition, we request that you:

- Please explain why JUUL uses nicotine salt e-liquids in its products; and

- Please explain why JUUL uses a nicotine concentration of 5% in its products.

Previous Document Requests

On April 24, 2018, the FDA sent you a request for documents relating to marketing practices and research on marketing, effects of product design, public health impact, and adverse experiences and complaints related to JUUL products.[41] It appears that the scope of FDA's request to JUUL is substantially similar to two requests from Congress.[42] However, based on reports,[43] JUUL has submitted a substantially greater number of documents to Congress than to FDA. Given the similarity in the scope of the requests, and the substantially greater number of documents apparently provided to Congress, we are concerned that JUUL has not provided the Agency relevant documents and information, and we are investigating the extent to which JUUL might not have provided the Agency documents responsive to its request.

FDA requests that you provide the Agency copies of any and all documents and information that JUUL provided, and that JUUL will provide, to Congress in response to the June 7, 2019, and April 8, 2019, requests. FDA also requests any additional information or documents provided to the Subcommittee prior to the aforementioned hearing, or in follow up to the hearing, including, but not limited to, questions for the record following the hearing.

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[41] April 24, 2018 letter from Matthew R. Holman, Ph.D., Director, Office of Science, Center for Tobacco Products, FDA, to Mr. Ziad Rouag, JUUL Labs, Inc. (Exhibit M).

[42] June 7, 2019 letter from U.S. Representative Raja Krishnamoorthi, Chairman, Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform of the U.S. House of Representatives, to Mr. Kevin Burns, CEO, JUUL Labs, Inc. (Exhibit N); April 8, 2019 letter from U.S. Senators Durbin, Murray, Wyden, Brown, Blumenthal, Reed, Warren, Udall, Markey, Merkley, and Van Hollen, to Mr. Kevin Burns, CEO, JUUL Labs, Inc. (Exhibit O).

[43] See, e.g., Matthew Perrone and Richard Lardner. "JUUL Exec: Never Intended Electronic Cigarette for Teens," Washington Post, July 25, 2019 (https://www.washingtonpost.com/politics/federal_government/juul-exec-facing-congressional-questions-over-teen-vaping/2019/07/25/394e5ba4-af0b-11e9-9411-a608f9d0c2d3_story.html?utm_term=.d8550c3258da) ("Drawing from some 180,000 documents collected from the company, House Democrats peppered Monsees with questions about the early ads and marketing that they contend led to the current wave of underage vaping by U.S. teens.").

Requested Actions

FDA requests that you provide the requested documents and information to the Agency within 30 days from the date of this letter. Due to the volume of documents, we encourage you to provide them on a rolling basis. For the purposes of all requests in this letter, in any instance where we refer to JUUL, we are also referring to any person or entity acting on JUUL's behalf or at its direction (e.g., agents, representatives, third-party contractors, consultants). In responding to these requests, please identify any and all documents and information that JUUL has not previously provided to FDA in response to any of its requests, including those under section 904(b) of the FD&C Act, those related to inspections, and those related to other correspondence and communication with the Agency. Where documents or information were previously provided to FDA, please reference the submission and document information.

We note FDA's outstanding July 1, 2019, request for documents and information regarding educational engagement and outreach, Tribal engagement and outreach, and additional marketing practices and marketing research activities by JUUL. We acknowledge that JUUL has been in communication with the Agency about this request and has agreed to provide the requested documents and information. To the extent that the July 1, 2019, request overlaps with the requests contained in this letter, JUUL will now have until 30 days from the date of this letter to provide the Agency the requested documents and information.

The requested documents and information should be submitted to the Agency in an electronic, searchable format. CD-ROM, DVD, or hard drive submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
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If you have questions regarding this request, please contact Anthony Villa, Senior Regulatory Counsel, Center for Tobacco Products, Office of Compliance and Enforcement, at (301) 796-7385 or via email at Anthony.Villa@fda.hhs.gov.

Sincerely,

/s/

Mitchell Zeller
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VIA Electronic Mail

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