

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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WASHINGTON, DC 20515-6143

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<https://oversight.house.gov>

November 13, 2020

K. C. Crosthwaite
Chief Executive Officer
Juil Labs, Inc.
560 20th Street
San Francisco, CA 94107

Dear Mr. Crosthwaite:

In light of alarming government research findings that menthol-flavored vaping products have become dangerously popular with illegal underage users, I am writing to urge JUUL to: (1) withdraw its Premarket Tobacco Product Application (PMTA) for a menthol-flavored product, and (2) produce to the Subcommittee on Economic and Consumer Policy a copy of JUUL's PMTA submission.

On July 30, 2020, JUUL Labs submitted its PMTA application to FDA, seeking permission to continue selling its Virginia Tobacco and menthol -flavored JUULpods.¹ JUUL had previously withdrawn from the market mint-flavored vaping products after federal research showed that a high percentage of young people preferred mint-flavored e-cigarettes. This year's findings similarly reveal that JUUL's menthol-flavored product will induce young people to use this illegal and harmful product. JUUL should act this year in a manner consistent with last year and withdraw this dangerous product from the market.

New Data Shows “Prominent Use” of Menthol-Flavored Vaping Products by High School Students

On September 18, 2020, the Centers for Disease Control and Prevention (CDC) released National Youth Tobacco Survey (NYTS) data showing that underage users of JUUL products have migrated to menthol. The findings “suggest prominent menthol e-cigarette use, including among nearly one half of flavored prefilled pod or cartridge users,” a category which JUUL dominates.² Alarming, 37% of high school e-cigarette users overall choose menthol-flavored products. This is a significant spike from 2019 when menthol was one of the least popular

¹ JUUL Labs, *Press Release: JUUL Labs Submits Premarket Tobacco Product Application to the U.S. Food and Drug Administration for the JUUL System* (July 30, 2020) (www.juul-labs.com/juul-labs-submits-premarket-tobacco-product-application/).

² Centers for Disease Control and Prevention, *E-cigarette Use Among Middle and High School Students—United States, 2020* (Sept. 18, 2020) (www.cdc.gov/mmwr/volumes/69/wr/mm6937e1.htm).

flavors, used by less than 6% of 12th graders, less than 3% of 10th graders, and less than 2.3% of eighth graders.³

Last year, the Monitoring the Future (MTF) survey, which is funded by the National Institute of Health, found that among users of JUUL e-cigarettes, “mint was the most popular flavor in 12th and 10th grades.” The MTF survey found that 47% of high school seniors preferred JUUL mint.⁴ Just two days after the MTF survey results were published showing the spike in youth use of JUUL’s mint product, JUUL expressed contrition and announced it would stop selling mint products:

In light of the studies released this week relating to the 2019 National Youth Tobacco Survey and Monitoring the Future survey, JUUL Labs’ CEO K.C. Crosthwaite announced that the company will immediately stop accepting orders from our retail partners for our Mint JUULpods in the U.S. and cease the sale of Mint JUULpods in the U.S. through our ecommerce site (JUUL.com).⁵

In your statement that day, you also stated:

These results are unacceptable and that is why we must reset the vapor category in the U.S. and earn the trust of society by working cooperatively with regulators, Attorneys General, public health officials, and other stakeholders to combat underage use.⁶

I am greatly concerned that this year, JUUL has not acted in a manner consistent with last year by withdrawing menthol-flavored products from the market in light of alarming recent data on youth preference for menthol. In fact, it has been 8 weeks since the CDC data revealed that menthol is as popular with kids today as your mint product was when you felt compelled to stop selling it. I call on JUUL to promptly withdraw its PMTA as it relates to JUUL’s menthol product to ensure that no FDA marketing order is granted for the menthol JUULpod flavor.

Transparency in JUULs PMTA Submission

On July 30, 2020, JUUL announced that it had submitted in its PMTA both a “scientific foundation for the FDA to evaluate whether these products are ‘appropriate for the protection of the public health’” and “data-driven measures to address underage use of its products.”⁷

³ *Flavors of E-Cigarettes Used by Youths in the United States*, JAMA Network (Nov. 5, 2019) (online at https://jamanetwork.com/journals/jama/fullarticle/2755264?guestAccessKey=6cd13a73-46aa-460e-95c7-0cb2d9b66fdf&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=fl&utm_term=110519).

⁴ *Id.*

⁵ JUUL Labs, *Press Release: JUUL Labs Stops the Sale of Mint JUULpods in the United States* (Nov. 7, 2019) (www.juulabs.com/juul-labs-stops-the-sale-of-mint-juulpods-in-the-united-states/).

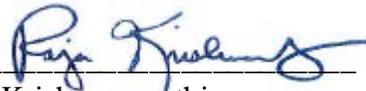
⁶ *Id.*

⁷ JUUL Labs, *Press Release: JUUL Labs Submits Premarket Tobacco Product Application to the U.S. Food and Drug Administration for the JUUL System* (July 30, 2020) (www.juulabs.com/juul-labs-submits-premarket-tobacco-product-application/).

The Subcommittee was encouraged to see that JUUL reiterated its desire to “work cooperatively with regulators, legislators, attorneys general, public health officials, and other stakeholders.”⁸ To demonstrate that sentiment, the Subcommittee requests that JUUL produce by November 16, 2020, its complete and unredacted PMTA submission(s) to FDA and all communications with FDA related thereto.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee’s request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Mike Cloud, Ranking Member

⁸ *Id.*

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.
2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.
3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.
4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.
5. Documents produced in electronic format should be organized, identified, and indexed electronically.
6. Electronic document productions should be prepared according to the following standards:
 - a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.
 - b. Document numbers in the load file should match document Bates numbers and TIF file names.
 - c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.
 - d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION,
BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.
8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.
9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.
10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.
11. The pendency of or potential for litigation shall not be a basis to withhold any information.
12. In accordance with 5 U.S.C. § 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.
13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.
14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.
15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.
16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.
17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.
19. All documents shall be Bates-stamped sequentially and produced sequentially.
20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.
21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term “document” means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.
4. The term “including” shall be construed broadly to mean “including, but not limited to.”
5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.
6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.
7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.
8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.
9. The term “individual” means all natural persons and all persons or entities acting on their behalf.