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ONE HUNDRED SIXTEENTH CONGRESS

JIM JORDAN, OHIO
RANKING MINORITY MEMBER

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6143
MAJORITY (202) 225-5051
MINORITY (202) 225-5074
http://oversight.house.gov

November 7, 2019

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

Dear Mr. Crosthwaite:

The Subcommittee is requesting documents and information about disturbing reports that JUUL Labs, Inc. (JUUL) may have knowingly sold nearly one million contaminated JUUL pods.

According to an attorney representing one former company executive, Siddharth Breja, his client became aware of "very concerning actions within the company that could be jeopardizing the health of millions of Juul users." According to his counsel, he "performed his duty to shareholders, the board, and the public by reporting these issues internally, expecting that Juul's senior management would do the right thing."[1]

In response, your company has asserted that "the product met all applicable specifications," including the "applicable specifications" to which you hold your product.[2]

Currently, the nation faces an outbreak of e-cigarette-related lung illness for which the Centers for Disease Control and Prevention (CDC) has not yet been able to identify the cause. CDC has identified 1888 cases of lung illness associated with the use of e-cigarette or vaping products in 49 states, the District of Columbia, and one U.S. territory. Thus far, the outbreak has resulted in at least thirty-seven deaths in 24 states.[3] As of August 7, 2019, the Food and Drug Administration (FDA) had received 127 reports of seizures and other neurological conditions caused by e-cigarette use.[4]

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[1] *JUUL Put 1 Million Tainted Pods into the Market, Former Executive Alleges in Lawsuit*, Washington Post (Oct. 30, 2019) (online at www.washingtonpost.com/business/2019/10/30/juul-put-million-tainted-pods-into-market-former-executive-alleges-lawsuit/).

[2] *Id.*

[3] Centers for Disease Control and Prevention, *Outbreak of Lung Disease Associated with E-Cigarette Use, or Vaping* (Oct. 31, 2019) (online at www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html).

[4] Food and Drug Administration, *In Brief: The Food and Drug Administration Encourages Continued Submission of Reports Related to Seizures Following E-cigarette Use as Part of Agency's Ongoing Scientific Investigation of Potential Safety Issue* (Aug. 7, 2019) (online at www.fda.gov/news-events/fda-brief/fda-brief-fda-

Simultaneous to the lung illness outbreak is the rise of youth e-cigarette use to epidemic levels. Undoubtedly, contaminated pods distributed by JUUL, the largest seller of e-cigarettes, would disproportionally put children at risk. Preliminary numbers from CDC's National Youth Tobacco Survey indicate that youth use of e-cigarettes has risen to an all-time high, with 27.5% of high school students reporting e-cigarette use. That is a 32% increase in the past year, and a 135% increase over two years.[5]

To examine the potential hazards of the contaminated pods your company reportedly distributed, the Subcommittee requests that you produce the following documents and information by November 21, 2019:

1. All documents referring or relating to any potentially or allegedly contaminated e-liquid related to Alternative Ingredients, Inc., or any other source, including any payments or requested payments related to potentially or allegedly contaminated e-liquid pod batches;

2. All documents referring or relating to JUUL's internal investigation of any "underlying manufacturing issue" and any findings reached regarding contaminated e-liquid pods;

3. All documents, including those involving Siddharth Breja, referring or relating to:

   a. e-liquid contamination;
   b. expiration of e-liquid pods;
   c. use of a "best by" date or date of manufacture; and
   d. a March 12, 2019, Executive Team Meeting;

4. A description of the internal reporting chain for defective products and the personnel hierarchy responsible for responding to such reports;

5. Your policies and product quality standards relating to when e-liquid is considered unacceptable for sale, and the steps you take after determining that a batch of e-liquid is unacceptable for sale;

6. A description of your testing procedures for e-liquid contamination, including frequency; and

7. All documents referring or relating to loss of sales and profits due to expired or contaminated e-liquid pods.

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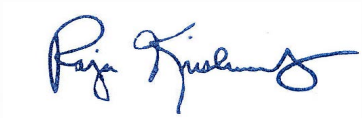
encourages-continued-submission-reports-related-seizures-following-e-cigarette-use).

[5] Food and Drug Administration, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019) (online at www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non).

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 Michael Cloud, Ranking Member

Responding to 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 Committees.

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 Committees' 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 Committees 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 Committees 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 Committees' 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 on Oversight and Reform, 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. When documents are produced to the Committee on Financial Services, production sets shall be delivered to the Majority Staff in Room 2129 of the Rayburn House Office Building and the Minority Staff in Room 4340 of the O'Neill House Office Building. When documents are produced to the Permanent Select Committee on Intelligence, production sets shall be delivered to Majority and Minority Staff in Room HVC-304 of the Capital Visitor Center.

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.