

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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<http://oversight.house.gov>

March 6, 2020

The Honorable Dr. Stephen M. Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

The Subcommittee on Economic and Consumer Policy is requesting documents and information about flavored, disposable e-cigarettes. Reports indicate that these products are gaining popularity among youth since the Food and Drug Administration (FDA) decided to exempt them from the guidance it issued on January 2, 2020.

FDA's guidance document on flavored e-cigarette products included wide exemptions.¹ The Subcommittee previously wrote to you on January 22, 2020, expressing concern that FDA's decision to exempt menthol from its partial flavor ban would cause youth to migrate to menthol.² We are equally concerned that FDA's decision to exempt disposable e-cigarettes from the partial flavor ban will undermine the purpose of the partial flavor ban. Disposable e-cigarettes, such as Puff Bar, STIG, and FOGG Vape are cheap, brightly colored, look like JUUL devices, and come in kid-friendly flavors such as Blueberry, Cool Mint, and Pineapple Lemonade.³

The Subcommittee is also concerned that FDA has disregarded its own rules. On May 16, 2018, FDA issued its final rule on tobacco regulation, which deemed all products that met the definition of "tobacco product" under the Federal Food, Drug, and Cosmetic Act to be subject to FDA's authority and subject to FDA enforcement action.⁴ The rule also set forth a compliance

¹ Food and Drug Administration, *Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (Jan. 2020) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market).

² Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Dr. Stephen Hahn, Commissioner, Food and Drug Administration (Jan. 22, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-01-22.RK%20to%20Hahn-FDA%20re%20Flavors%20Ban%20%281%29.pdf>).

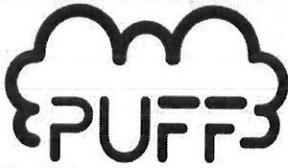
³ *Teens Are Still Vaping Flavors, Thanks to New Disposable Vape Pens*, National Public Radio (Feb. 17, 2020) (online at www.npr.org/sections/health-shots/2020/02/17/805972087/teens-are-still-vaping-flavors-thanks-to-new-disposable-vape-pens).

⁴ 61 Fed. Reg. 28973.

policy that applied only to tobacco products that were on the market as of August 8, 2016.⁵ If a tobacco product entered the market after August 8, 2016, the product is not permitted to be sold on the market, and FDA may pursue enforcement action to remove it from the market.⁶

Some of today's most popular disposable e-cigarettes do not appear to have been on the market as of August 8, 2016. Puff Bar, which markets disposable e-cigarettes coming in flavors such as Pink Lemonade, Strawberry, and Watermelon, states on its website that it was "[f]ounded in 2019 in Los Angeles, CA."⁷ Puff Bar's Articles of Incorporation, dated May 1, 2019, confirm that fact.⁸ Puff Bar filed for Trademark protection on January 27, 2020.⁹ In light of these facts, Puff Bar appears to be in violation of FDA's deeming rule and subject to enforcement action.

TSDR	ASSIGN Status	TTAB Status	(Use the "Back" button of the Internet Browser to return to TESS)
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Word Mark PUFF
Goods and Services IC 003. US 001 004 006 050 051 052. G & S: Body lotion; Bath oils; Body oils
IC 029. US 046. G & S: Edible oils
IC 030. US 046. G & S: Gummy candies; Flavor enhancers used in food and beverage products
IC 032. US 045 046 048. G & S: Fruit flavoured drinks; Soft drinks
IC 034. US 002 008 009 017. G & S: Electronic cigarettes; Flavorings, other than essential oils, for use in electronic cigarettes; Liquid nicotine solutions for use in electronic cigarettes
Mark Drawing Code (3) DESIGN PLUS WORDS, LETTERS, AND/OR NUMBERS
Design Search Code 01.15.06 - Advertising, skywriting ; Clouds ; Fog
Serial Number 68775076
Filing Date January 27, 2020
Current Basis 1B
Original Filing Basis 1B
Owner (APPLICANT) Cool Clouds Distribution, Inc. CORPORATION CALIFORNIA 316 E 4th Street 316 E 4th Street Los Angeles CALIFORNIA 90013
Attorney of Record Todd Gallinger
Description of Mark Color is not claimed as a feature of the mark. The mark consists of the word "PUFF" in stylized letters surrounded by stylized cloud design that is open at the bottom.
Type of Mark TRADEMARK
Register PRINCIPAL
Live/Dead Indicator LIVE

Puff Bar is also selling a product, Puff Krush, which appears to be a new tobacco product specifically designed to circumvent FDA's partial flavor ban. Puff Krush can be added onto other vaping devices, converting them into flavored products. The Puff Krush packaging shows

⁵ *Id.*

⁶ Food and Drug Administration, *How FDA is Regulating E-Cigarettes* (Sept. 10, 2019) (online at www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulating-e-cigarettes).

⁷ Puff Bar, *About Us* (online at <https://puffbar.com/pages/about-puff-bar>) (accessed Feb 20, 2020).

⁸ California Secretary of State, *Business Search for Cool Clouds Distribution, Inc.* (accessed Feb. 14, 2020) (online at <https://businesssearch.sos.ca.gov/Document/RetrievePDF?Id=04272932-26198115>).

⁹ United States Patent and Trademark Office, *Word Mark for Puff* (accessed Feb. 14, 2020) (online at <http://tmsearch.uspto.gov/bin/showfield?f=doc&state=4808:xxvigp.2.21>).

the device being inserted onto an image of a JUUL device, and Puff Bar markets them as “produced to function with nicotine salt devices.”¹⁰



The Subcommittee also questions whether STIG Pods, which come in flavors such as Tropical Mango, Mighty Mint, and Lush Ice, were on the market on August 8, 2016. FDA appears to have shared this concern—on October 12, 2018, FDA sent a letter to VGOD, Inc. requesting that the company provide evidence that STIG Pods were on the market on August 8, 2016, and have not been modified.¹¹

As stated in my January 22, 2020, letter to you, the Subcommittee is concerned about FDA’s ability to rapidly detect whether children are migrating to different flavors or different products, which may limit FDA’s ability to make timely changes to its policies.

Today, the Subcommittee is sending letters to three of the manufacturers of popular disposable e-cigarettes: Puff Bar, STIG, and FOGG Vape. The Subcommittee has previously written to two other manufacturers of flavored, disposable e-cigarettes: Blu and NJOY. We have asked all five of these companies to voluntarily stop selling their flavored, disposable e-cigarettes.

The Subcommittee encourages FDA to investigate whether children are moving to these products. If they are, I believe it is your duty to pull these products from shelves. At a minimum, the Subcommittee urges you to investigate whether Puff Bar, Stig, and Fogg Vape were on the market prior to August 8, 2016. If they were not, the Subcommittee believes that you have the obligation to clear them from the market.

¹⁰ Puff Krush, *Home Page* (online at www.puffsalt.com/collections/puff-krush) (accessed Feb. 20, 2020).

¹¹ Letter from Ann Simoneau, Director, Office of Compliance and Enforcement, Center for Tobacco Products, Food and Drug Administration, to Waleed Aloteibi, President, VGOD, Inc. (Oct. 12, 2018) (online at www.fda.gov/media/117551/download).

In order to evaluate this matter further, please provide the following information by Friday March 20, 2020:

1. A description of all tools FDA plans to utilize to monitor youth use of disposable e-cigarettes, including for each tool:
 - a. when FDA will implement it;
 - b. how FDA intends to gather information;
 - c. over what time period will information be gathered; and
 - d. when FDA expects to receive disposable e-cigarettes use data from the tool;
2. All documents provided in response to FDA's October 12, 2018, letter to VGOD, Inc. (Submission Tracking Number: TC0003973);
3. A list of all e-cigarettes on the market as of August 8, 2016; and
4. A statement about whether:
 - a. Current Puff Bar, STIG, and FOGG Vape offerings were on the market on August 8, 2016;
 - b. FDA is currently pursuing enforcement actions against any disposable e-cigarette manufacturers for not being on the market on August 8, 2016; and
 - c. FDA will commit to immediately clearing the market of disposable e-cigarette products that were not deemed products on the market on August 8, 2016.

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.