

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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June 1, 2020

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

Dear Commissioner Hahn:

On April 1, 2020, the Subcommittee wrote to request that the Food and Drug Administration (FDA) clear the market of e-cigarettes during the coronavirus crisis. As that letter explained, allowing e-cigarettes to remain on the market during this period harms children and adults throughout the country and exacerbates the coronavirus crisis in critical ways. For these reasons, the Subcommittee asked FDA to take the following steps during the coronavirus crisis: (1) use all available tools to encourage Americans to stop smoking combustible cigarettes and using e-cigarettes; (2) suspend all approvals of Premarket Tobacco Product Applications (PMTA); and (3) commit to immediately clearing the market of all e-cigarettes by prioritizing enforcement against them.¹ In a briefing to Subcommittee staff, FDA said that it would not clear the market of e-cigarettes during the coronavirus crisis, and would not commit to suspending PMTA approvals.²

Today, the Subcommittee is writing to request that FDA use its full legal authority to immediately remove from the market flavored e-cigarette products sold by a company known as Puff Bar, which appears to be taking advantage of the coronavirus crisis to explicitly—and illegally—sell its products to school children. Puff Bar is quickly becoming the new JUUL. It is cheap and brightly colored, resembles a JUUL device, and comes in kid-friendly flavors like Mango, Banana Ice, Pink Lemonade, Blue Razz, and O.M.G.³ You owe it to the public health to

¹ 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 (Apr. 1, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-04-01.RK%20to%20Hahn-FDA%20re%20Vaping%20and%20Coronavirus.pdf>).

² Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, Press Release: FDA Rejects Subcommittee's Call to Temporarily Remove E-Cigarettes Despite Potential Risks to Coronavirus Patients (Apr. 17, 2020) (online at <https://oversight.house.gov/news/press-releases/fda-rejects-subcommittee-s-call-to-temporarily-remove-e-cigarettes-despite>).

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).

act now, particularly in light of evidence demonstrating how e-cigarettes lead to worse outcomes for coronavirus patients.⁴

This marks the second time that the Subcommittee has written to you about Puff Bar.⁵ I hope that the company's increasingly troubling actions convince you that FDA action is necessary.

Puff Bar Marketing Directly to Kids During Coronavirus Crisis

Puff Bar has been distributing the following advertisement with a “solo break” theme, an image of a bedroom, and a message to “escape ... parental texts.” The advertisement is designed to convince children home from school to vape in their rooms without their parents noticing.

From: Team Puff Bar <info@puffbar.com>
Date: April 29, 2020 at 6:30:31 PM EDT
To: Newsletter Subscriber <[REDACTED]>
Subject: The first solo-spring break... with Puff Bar

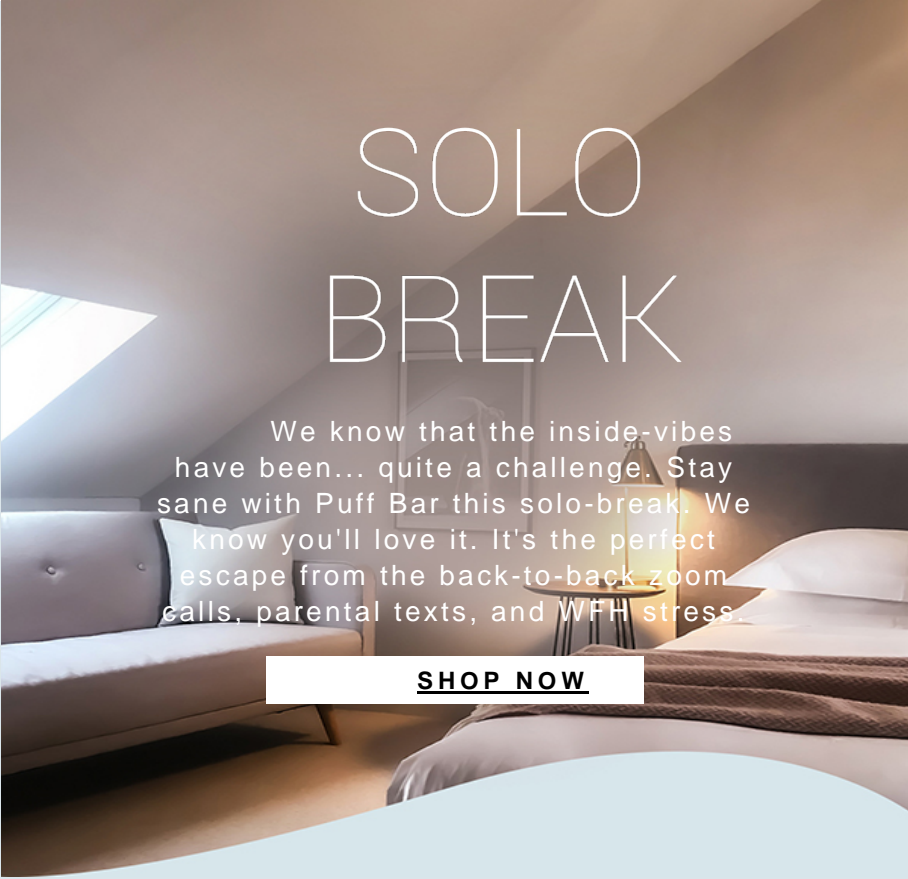


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⁴ Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Dr. Stephen Hahn, Commissioner, Food and Drug Administration (Apr. 1, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-04-01.RK%20to%20Hahn-FDA%20re%20Vaping%20and%20Coronavirus.pdf>).

⁵ 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 (Mar. 6, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-03-06.RK%20to%20Hahn-FDA%20re%20E-Cig%20Exemptions.pdf>).



SOLO BREAK

We know that the inside-vibes have been... quite a challenge. Stay sane with Puff Bar this solo-break. We know you'll love it. It's the perfect escape from the back-to-back zoom calls, parental texts, and WFH stress.

[**SHOP NOW**](#)

THE PERFECT MIX



Drop in and shop our top flavors today. You won't be disappointed. There's a reason that we've been one of the top, highest growing e-cig brands in the world. Our earth-friendly, independently sourced, unique flavor combinations are guaranteed to please. Puff puff, buy (don't pass) before we sell out for the 4th time this year again.

[SHOP NOW](#)


Puff Bar has exploited a confluence of events to sell its products: (1) when FDA issued a partial flavor ban on e-cigarettes earlier this year, it barred pod-based products like JUUL from selling flavors other than tobacco or menthol, but it created a wide exemption that allowed disposable products to continue selling flavors, opening the flood gates for companies like Puff Bar to market flavored e-cigarettes; (2) FDA extended the period of Puff Bar's dominant position in the flavored e-cigarette market by delaying from May 12, 2020, to September 9, 2020, the date by which all e-cigarettes need to apply to FDA to stay on the market, effectively freezing the status quo; and (3) coronavirus has both drawn the attention of FDA away from tobacco products regulation and provided an addictive pastime for kids.

Apparently Illegal Sales of Puff Bar Products

Every Puff Bar sold in America appears to be sold illegally. FDA's enforcement policy allows FDA to immediately remove all such products from the market. On May 16, 2018, FDA 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. This rule set forth a compliance policy that applied only to tobacco products that were on the market

as of August 8, 2016.⁶ Any tobacco product that entered the market after that date is not permitted, and FDA may pursue enforcement action to remove it from the market.⁷

Puff Bar states on its website that it was “Founded in 2019 in Los Angeles, CA.”⁸ It also states: “After months of trial and error, Puff Bar came to life in Los Angeles, CA in 2019.”⁹ Puff Bar’s Articles of Incorporation, which are set forth below, are dated May 1, 2019.¹⁰

 Secretary of State Articles of Incorporation of a General Stock Corporation	ARTS-GS	4272932
IMPORTANT — Read Instructions before completing this form. Filing Fee — \$100.00 Copy Fees. — First page \$1.00; each attachment page \$0.50; Certification Fee - \$5.00 <i>Note: Corporations may have to pay minimum \$800 tax to the California Franchise Tax Board each year. For more information, go to https://www.ftb.ca.gov.</i>		FILED <i>mc</i> Secretary of State State of California MAY 01 2019 <i>10</i>
<i>lpc</i> This Space For Office Use Only		
1. Corporate Name (Go to www.sos.ca.gov/business/be/name-availability for general corporate name requirements and restrictions.)		
The name of the corporation is <u>Cool Clouds Distribution, Inc.</u>		

In addition, as set forth below, Puff Bar filed for trademark protection on January 27, 2020.¹¹

⁶ 61 Fed. Reg. 28973.

⁷ 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).


⁸ Puff Bar, *About Us* (online at <https://puffbar.com/pages/about-puff-bar>) (accessed May 21, 2020).

⁹ Puff Bar, *Official Blog: Who Makes Puff Bar* (Jan. 13, 2020) (online at <https://puffbar.com/blogs/vape-news/who-makes-puff-bar>).

¹⁰ 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>).

¹¹ 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>).

TSDR ASSIGN Status TTAB Status (Use the "Back" button of the Internet Browser to return to TESS)



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 88775076
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

As a result, Puff Bar appears to be in direct violation of FDA’s deeming rule and subject to enforcement action.

Puff Bar has also changed its design after entering the market. Its website states that “Every day, we look at ways to improve our products.”¹² In the FAQ section, the company includes the following comparison between its original design, the Puff Bar, and its newer design, the Puff Bar Plus:

Puff Bar: This is the original Puff Bar, the one you know and love.
Puff Bar Plus: Puff Bar Plus takes your favorite parts of our original device and makes them even better. More hits, more liquid, more battery life, all in the same compact size you’re used to.¹³

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, set forth below, shows the device being inserted onto an image of a JUUL device, and Puff Bar markets them as “produced to function with nicotine salt devices.”¹⁴

¹² Puff Bar, *About Us* (online at <https://puffbar.com/pages/about-puff-bar>) (accessed on May 1, 2020).

¹³ Puff Bar, *Official Blog: Everything You Ever Wanted to Know About the Puff Bar Disposable Device* (Jan. 15, 2020) (online at <https://puffbar.com/blogs/vape-news/puff-bar-101-everything-you-ever-wanted-to-know-about-the-puff-bar-disposable-device>).

¹⁴ Puff Krush, *Home Page* (online at www.puffsalt.com/collections/puff-krush) (accessed Feb. 20, 2020).



Now that FDA has delayed from May to September the date by which it must receive premarket tobacco product applications, FDA has more time to address this enforcement matter. Puff Bar is not hiding its illegal behavior. If Puff Bars were not sold prior to August 16, 2016, FDA should pull them from the shelves and take all other appropriate action against the company.

Unapproved Modified Risk Claims and Unauthorized Marketing as Smoking Cessation Device

Manufacturers of tobacco products are prohibited from claiming that their products are healthier or safer than cigarettes (“modified risk claims”) unless they apply for, and receive, approval from FDA. Making modified risk claims without FDA approval violates Section 911 of the Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act.¹⁵

Although it does not appear that Puff Bar has obtained FDA approval, the company has been making multiple modified risk claims by stating that its product is safer than cigarettes. For example:

¹⁵ Food and Drug Administration, *Section 911 of the Federal Food, Drug, and Cosmetic Act-Modified Risk Tobacco Products* (Jan. 7, 2018) (online at www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-911-federal-food-drug-and-cosmetic-act-modified-risk-tobacco-products) (“No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product,” and defining “modified risk tobacco product” as “any tobacco product that is sold or distributed for use to reduce harm of the risk of tobacco-related disease associated with commercially marketed tobacco products”).

- In an official blog post on Puff Bar’s website, the company states: “Puff Bar was founded with three core values in mind: simplicity, value, and offering a healthier alternative to cigarettes.”¹⁶
- The “About Us” section of Puff Bar’s website states: “Puff Bar bases its company on three main values: simplicity, value and—most importantly—what we believe is a healthier alternative to smoking traditional cigarettes.”¹⁷
- In another blog post, the company asserts: “A Puff Bar is a disposable all-in-one vape device. Think of it as a cheaper, more convenient alternative to smoking a cigarette. Also minus the endless, ongoing list of negative effects on your health that come with smoking.”¹⁸

In addition, claims that a product helps users quit smoking are “therapeutic claims, subject to FDA jurisdiction under the drug/device provisions of the Food, Drug, and Cosmetic Act. Such drugs or devices must be approved by FDA, and if they are not, they are unapproved drugs or devices being marketed illegally.¹⁹ Puff Bar is making therapeutic claims. For example, on its website, Puff Bar states: “The most important thing Puff Bar aims to do is help people quit smoking cigarettes.”²⁰

¹⁶ Puff Bar, *Official Blog: Who Makes Puff Bar* (Jan. 13, 2020) (online at <https://puffbar.com/blogs/vape-news/who-makes-puff-bar>) (emphasis added).

¹⁷ Puff Bar, *About Us* (online at <https://puffbar.com/pages/about-puff-bar>) (accessed on May 21, 2020) (emphasis added).

¹⁸ Puff Bar, *Official Blog: Everything You Ever Wanted to Know About the Puff Bar Disposable Device* (Jan. 15, 2020) (online at <https://puffbar.com/blogs/vape-news/puff-bar-101-everything-you-ever-wanted-to-know-about-the-puff-bar-disposable-device>) (emphasis added) (also stating that its product is being made from “medical-grade cotton” and that the product produces “no carcinogens because there is no burning material”).

¹⁹ 21 U.S.C. § 321(g); *Sottera Inc. v. Food and Drug Administration*, 627 F. 3d 891 (U.S. App. DC 2010); Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices or Combination Products; Amendments to Regulations Regarding “Intended Uses,” 82 Fed. Reg. 2193 (Jan. 9, 2017) (“A product will be regulated as a drug, device or combination product if: (a) The product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, **including use in the cure or treatment of nicotine addiction (e.g. smoking cessation)**, relapse prevention, or relief of nicotine withdrawal symptoms” (emphasis added), and “statements related to quitting smoking generally create a strong suggestion that a product is intended for a therapeutic purpose.”).

²⁰ Puff Bar, *Official Blog: Who Makes Puff Bar* (Jan. 13, 2020) (online at <https://puffbar.com/blogs/vape-news/who-makes-puff-bar>).

Request for FDA to Take Action

When FDA decided to allow disposable e-cigarettes to continue to be sold in kid-friendly flavors, FDA's Director of the Center for Tobacco Products, Mitch Zeller, stated: "Let's be clear: Under this policy, if we see a product that is targeted to kids, we will take action."²¹ Now is the time to put those bold words into action. To assist the Subcommittee in its review of this matter, please answer the following questions by June 12, 2020:

1. Which Puff Bar products were on the market as of August 8, 2016, and what is your basis for making that determination? If you do not yet know the answer to this question, what steps have you taken to determine the answer, and when do you anticipate being able to make a conclusion?
2. Has FDA ever been in communication with Puff Bar? If so, with which individuals representing Puff Bar did you communicate? Was the company cooperative and responsive to your requests? Did your communications address the issues raised in this letter?
3. Does FDA have nationally representative data from the 2020 National Youth Tobacco Survey (NYTS)? If so, when will you release the preliminary data?
4. Based on the NYTS, or any other source, are youth migrating to Puff Bar and other disposable products?
5. What is FDA's justification for not removing Puff Bar products from the market?

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. 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

cc: The Honorable Michael Cloud, Ranking Member

²¹ *Teens Find a Big Loophole in the New Flavored Vaping Ban*, Chicago Tribune (Jan. 1, 2020) (online at www.chicagotribune.com/featured/sns-nyt-teens-find-loophole-flavored-vaping-ban-20200131-ttxn57xu45elxgyjaenfb5dc6u-story.html).