## 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 https://oversight.house.gov

March 3, 2021

Dr. Janet Woodcock Acting Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock:

The Subcommittee on Economic and Consumer Policy is writing to inform you that despite a clear warning from the Food and Drug Administration (FDA), Puff Bar e-cigarettes are still being sold illegally. We call on you to take all appropriate action to remove Puff Bar products from the market and to punish those responsible for putting youth at risk by ignoring FDA's directive to stop sales. We encourage you to consider all available enforcement tools, including seizure, injunction, and criminal prosecution.

On March 6, 2020, the Subcommittee initially presented evidence to FDA that all U.S. sales of Puff Bar products were illegal and subject to immediate FDA enforcement action.<sup>1</sup>

On June 1, 2020, the Subcommittee presented FDA with further evidence that sales of Puff Bar products were illegal and subject to immediate enforcement action. We also presented evidence that the sellers of Puff Bar were exploiting the pandemic and using it as an opportunity to market their product directly to children. And we further presented evidence that Puff Bar was illegally marketing its products as healthier or safer than cigarettes (modified risk claims) and as smoking cessation devices (therapeutic claims).<sup>2</sup>

In response to the Subcommittee's efforts, around July 13, 2020, the Puff Bar website displayed a banner proclaiming that Puff Bar had ceased all online sales and distribution in the United States:<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> 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).

<sup>&</sup>lt;sup>2</sup> 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 (June 1, 2020) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-06-01%20RK%20to%20Hahn-%20FDA%20Puff%20Bar%20Products.pdf).

<sup>&</sup>lt;sup>3</sup> PUFF, Home Page (online at https://web.archive.org/web/20200721152019/https://puffbar.com/).



Shortly thereafter, FDA sent a July 20, 2020, warning letter to Cool Clouds Distribution Inc. (doing business as Puff Bar). FDA declared Puff Bar's products to be adulterated because they are new tobacco products being sold without a marketing order and are misbranded because the required notice was not provided to FDA prior to sale. FDA further found that the products were adulterated because of illegal modified risk claims.<sup>4</sup> I issued a statement that day supporting FDA's action.<sup>5</sup>

Unfortunately, Puff Bar sales have resumed (if they ever actually stopped). On February 19, 2021, individuals who were subscribed to Puff Bar's email update listserv received the following email touting a "New Launch," declaring that "we're back!," and encouraging people to "shop our <u>new</u> arrivals" (emphasis added):

Begin forwarded message:

From: Puff Bar <info@puffbar.com>
Subject: ""We're back" fresh launch alert just for you...
Date: February 19, 2021 at 5:03:05 PM EST
To: Newsletter Subscriber <

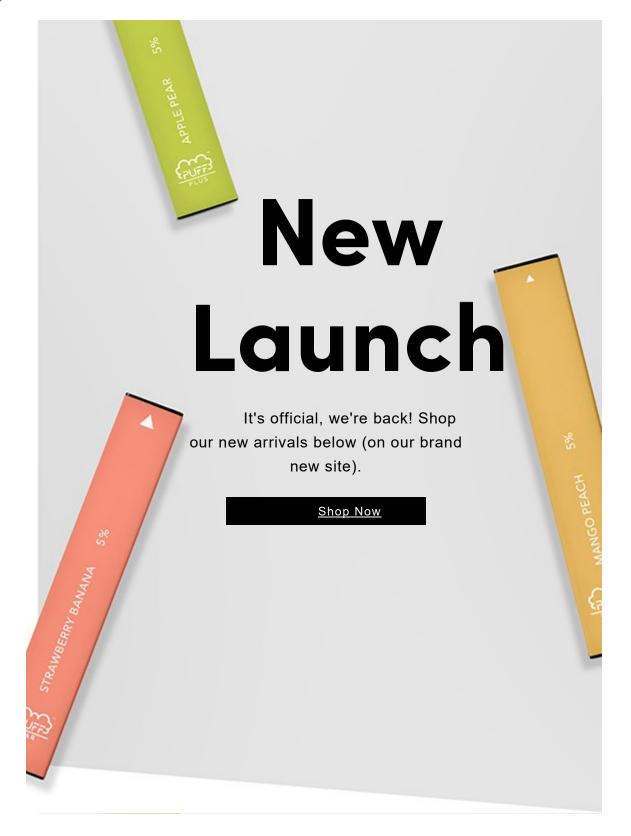


<u>VIEW IN BROWSER</u>

SHOP ABOUT LEARN

<sup>&</sup>lt;sup>4</sup> Food and Drug Administration, *Warning Letter to Cool Clouds Distribution, Inc. d/b/a/ Puff Bar* (July 20. 2020) (online at www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cool-clouds-distribution-inc-dba-puff-bar-608526-07202020).

<sup>&</sup>lt;sup>5</sup> Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: FDA Follows Chair Krishnamoorthi's Lead, Calls on Puff Bar to Remove Products* (July 20, 2020) (online at https://oversight.house.gov/news/press-releases/fda-follows-chair-krishnamoorthi-s-lead-calls-on-puff-bar-to-remove-products).



# **New Arrivals**



## **PUFF BAR**

An upgraded Puff from our classic version. Enjoy.

SHOP NOW

## **PUFF PLUS**

Bigger, and better, than ever.

SHOP NOW





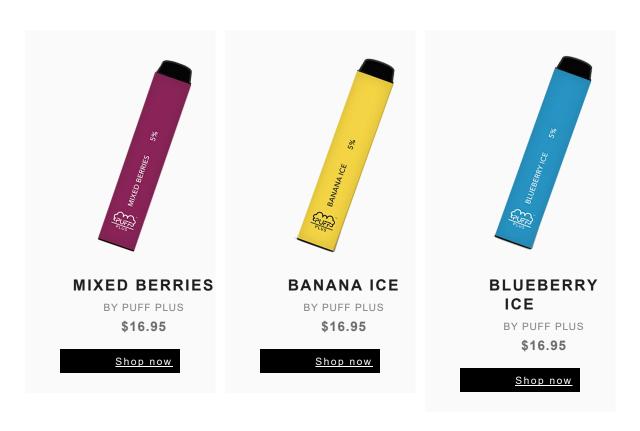
# **PUFF NANO**

For those smaller, but mighty, moments.

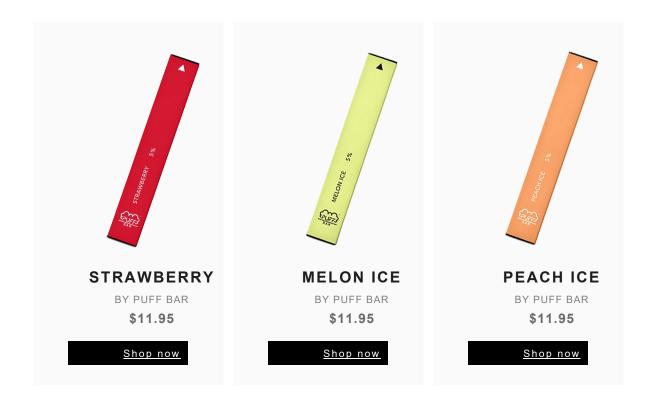
SHOP NOW

# Shop all our Restock Flavors

## Puff Bar plus

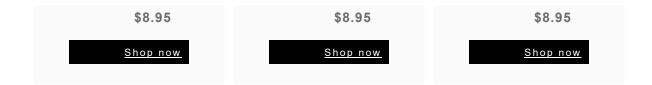


Puff Bar



Puff Bar Nano





# We've got you covered



WARNING: This product contains tobacco-free nicotine. Tobacco-free nicotine is an addictive chemical.

WARNING: Contains tobacco-free nicotine, which can be poisonous. Avoid contact with skin and eyes. Do not drink. Keep out of reach of children and pets. In case of accidental contact, seek medical help.

**CALIFORNIA PROPOSITION 65 WARNING:** 

This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. Puff Bar is committed to ensuring tobacco-free nicotine products stay out of the hands of minors. In addition to verifying the age of our shoppers, we comply with various state and local laws, require additional shipping obligations, or impose various taxes. The list of laws and regulations that we comply with may change without notice as any additional laws are enacted.

Again, if you are receiving this email, you confirmed that you are 21 years of age or older via our website. If you are not 21+, please unsubscribe.

THIS PRODUCT IS NOT DERIVED FROM TOBACCO OR INTENDED TO BE USED WITH ANY TOBACCO PRODUCTS.

W W W . P U F F B A R . C O M

251 Little Falls Drive Wilmington County, DE 19808

Email preferences Unsubscribe Terms of service Privacy policy

These sales are as illegal today as they were when FDA first declared them to be illegal on July 20, 2020.

Further, Puff Bar is compounding the illegality by now falsely claiming that its tobacco products are "tobacco free." Its webpage includes the following:



### **DS** Technology Licensing and Todd Gallinger

A Delaware company called DS Technology Licensing, LLC now appears to own the registered trademarks for Puff Bar and multiple related marks. It has even taken the brazen step of suing other companies using the marks to imitate its illegal products.<sup>7</sup>

DS Technology is represented by attorney Todd Gallinger of Gallinger Law. Mr. Gallinger also represented Cool Clouds Distribution. In telephone conversations with Mr. Gallinger he explained that Cool Clouds sold the Puff Bar IP rights to DS Technology Licensing, and that the latter is the successor company of the former. Mr. Gallinger claims to have represented both parties to the transaction transferring IP rights, and in general appears to have an undisclosed vested interest in Puff Bar that warrants FDA's further investigation into who to hold accountable. The transfer of IP rights may have been a sham transaction. A Racketeer Influenced and Corrupt Organizations Act (RICO) case filed against Puff Bar alleges that the same individuals control both organizations: Abdurrahman Yousef (a felon, convicted of trafficking in contraband tobacco products and mail fraud), Umais Abu Baker, Saquib Shoaib, and Adnan Shoaib.

<sup>&</sup>lt;sup>6</sup> Puff, *About Page* (online at https://puffbar.com/pages/about) (accessed Feb. 25, 2020).

<sup>&</sup>lt;sup>7</sup> *Puff Bar Owner Sues Over Fake Products*, Tobacco Reporter (Oct. 2, 2020) (online at https://tobaccoreporter.com/2020/10/02/puff-bar-owner-sues-over-fake-products/).

<sup>&</sup>lt;sup>8</sup> Vapor Exotica Group, LLC v. Abdurrahman Yousef, Civ. Case No. 20STCV45123 (Cal. Super. Ct., County of Los Angeles) (2021).

There are also reports that Puff Products are made by a Chinese company called Shenzen Daosen Steam Technology Co., Ltd., also known as "DS Vaping." <sup>9</sup>

#### **Request for FDA to Take Further Action**

The Subcommittee is confident that, armed with this information, FDA will bring appropriate action against all companies and individuals responsible for the sale of Puff Bar, which are evading the clear message laid down in FDA's July 20, 2020, warning letter, to clear the market of Puff Bar.

We encourage you to go beyond simply shutting down DS Technology Licensing—FDA must use all tools at its disposal, including seizure, injunction, and criminal prosecution, to hold accountable the individuals responsible for these flagrant violations of law. If individuals caught breaking the law face no penalty, and are able to keep ill-gotten gains, the law will continue to be ignored. This is the opportunity to set a new standard going forward.

Please contact Subcommittee staff by March 10, 2021, to schedule a staff briefing on this matter.

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

<sup>&</sup>lt;sup>9</sup> Lifting the Veil on a Controversial E-Cigarette Company—Sort Of, Fair Warning (July 9, 2020) (online at www.fairwarning.org/2020/07/veil-lifted-on-controversial-e-cigarette-company/).