

American Academy
of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



American
Heart
Association.



March 18, 2021

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

RE: Synthetic nicotine and Puff Bar

Submitted via e-mail

Dear Dr. Woodcock:

We write today about a matter of great urgency and time sensitivity. In a clear effort to circumvent any regulation by FDA, a very popular product among youth, Puff Bar, has just announced that it has reintroduced its “disposable” nicotine-based e-cigarette. Puff Bar claims it is now made with “a patented manufacturing process, not from tobacco.”¹ FDA previously asserted jurisdiction over, and took enforcement action against, Puff Bar as a tobacco product because the nicotine it contained was derived from tobacco, forcing the manufacturer to remove Puff Bar from the market.²

Whether Puff Bar is under the jurisdiction of the Center for Drug Evaluation and Research (CDER) as a drug or the Center for Tobacco Products (CTP) as a tobacco product, it is critical that FDA take action and not permit this company and this product to escape regulatory oversight. Puff Bar has neither been approved as a drug nor received a premarket tobacco product order. The agency should not allow any perceived regulatory “gap” to enable this company or any other company to market new addictive nicotine products without going through the legally required FDA review by either CDER or CTP.

The undersigned organizations believe that these synthetic nicotine products clearly fit within the definition of a drug and must be regulated as such. However, whether regulated as drugs or as tobacco products, these products are on the market illegally and must be removed immediately through enforcement action.

In a letter to FDA dated November 6, 2018, the Campaign for Tobacco-Free Kids demonstrated that synthetic nicotine products are drugs. We incorporate that letter by reference here and include it as an appendix to this letter. Under the Federal Food, Drug and Cosmetic Act (FDCA), a product delivering nicotine that is not derived from tobacco (and therefore is not a tobacco product under the definition of tobacco product in the FDCA) is a drug because it is intended to affect the structure and function of the body.

FDA must not lose sight of the real-world public health consequences of regulatory inaction over these synthetic nicotine products. As FDA is well aware, the most recent NYTS data show that in 2020 youth use of disposable e-cigarettes increased 1000% over the previous year. According to market data, Puff Bar was the most popular disposable e-cigarette brand among young people during that time.³ Additionally, the Centers for Disease Control and Prevention (CDC) and FDA just released data indicating that among middle school and high school current e-cigarette users, disposable e-cigarettes were the only device type that saw an increase in usage in 2020.⁴ ITC Youth Tobacco & Vaping Survey data from August 2020 show that Puff Bar has replaced JUUL as the most popular e-cigarette brand among youth and young adult past 30-day e-cigarette users. Puff Bar was preferred by 24% of users ages 16-19 vs 21% for JUUL.⁵ Further, 72.6% of disposable e-cigarette sales during that time period were for flavors that were otherwise banned in pod-based e-cigarettes.³

FDA sent a warning letter to Puff Bar in July 2020, after which the company claims to have stopped online U.S. sales. Nonetheless, Nielsen data still show Puff Bar products have continued to capture a significant portion of the disposable market. There is some dispute whether some of those were counterfeit products,⁶ but the fact remains that flavored, disposable e-cigarettes continue to gain and/or maintain market share.^{7,8} Now Puff Bar claims to be “back” with 5% nicotine products in kid-friendly flavors not permitted in cartridge-based products. It is FDA’s responsibility to take action to prohibit the sale of these illegal products which are harmful to children.

Rarely is an effort to escape FDA jurisdiction so blatant. Puff Bar previously sought to evade regulation as a tobacco product by withdrawing from the market because it could not meet FDA’s public health standard for tobacco products. Now the manufacturer claims to have reformulated the product so that it contains synthetic nicotine. Thus, by marketing its product without authorization of any type, it is acting in a manner that is inconsistent with the rules governing drugs and tobacco products. In addition, the company’s promotional e-mail to consumers announcing its new product leaves no doubt that Puff Bar seeks to avoid CTP jurisdiction: “THIS PRODUCT IS NOT DERIVED FROM TOBACCO OR INTENDED TO BE USED WITH ANY TOBACCO PRODUCTS”.⁹ It repeats this theme on its website: “All PuffBar products listed on this website contain nicotine but do not contain tobacco or anything derived from tobacco.

PuffBar products are not intended for use with any tobacco product or any component or part of a tobacco product.”¹⁰

At the same time, the company seeks to avoid FDA’s regulatory oversight as a drug, stating on its website:

WARNING: PuffBar products are not intended to diagnose, treat, cure or prevent any disease, condition, or disorder and are not smoking cessation or nicotine replacement therapy products. The FDA has not reviewed these products, nor has it evaluated their safety or any of the statements made regarding these products. PuffBar products contain nicotine, which is a highly addictive substance, and are intended to be used only by adults at least 21 years of age who use combustible cigarettes or other tobacco or nicotine vaping products. Do not use PuffBar products if you are pregnant or nursing, if you have heart disease, high blood pressure, diabetes, ulcers, liver or kidney disease, throat disease, asthma, or difficulty breathing. Do not use PuffBar products if you are taking theophylline, ropinirole, or clozapine. As with other nicotine products, use of PuffBar products can increase your heart rate and blood pressure and may cause nausea or dizziness or aggravate existing respiratory conditions. Use of PuffBar products may expose you to certain chemicals identified as harmful and/or carcinogenic, including aldehydes, volatile organic compounds, and metals.¹⁰

The definition of a drug under 21 U.S.C. § 321(g) includes, *inter alia*, “articles (other than food) intended to affect the structure or any function of the body of man or other animals.” Here, there is no doubt that Puff Bar’s manufacturer is aware of nicotine’s pharmacological effects. The warning quoted above states this, and indeed, producing those effects is the entire purpose of Puff Bar. And while the presence of nicotine alone is sufficient evidence of the manufacturer’s intent, the company’s website states plainly that Puff Bar delivers “the same satisfaction smokers are seeking from their nicotine.”¹ As explained in the attached letter from 2018, this is sufficient to qualify Puff Bar as a drug under the FDCA.

We are concerned that FDA’s failure to respond to questions about the regulatory status of Puff Bar could delay regulatory enforcement action and invite copycat products. Both in response to questions at the recent SRNT annual conference, and from the press, FDA spokespeople have indicated that FDA is aware of the issue of synthetic nicotine, and Puff Bar products specifically, but must conduct a case-by-case review to determine whether they are a tobacco product.^{6,11}

The lack of a clear position on the regulatory status of synthetic nicotine creates a dangerous loophole that will enable this manufacturer to market these addictive products to youth and young people. Under the current statutory regime, FDA should conclude that these synthetic nicotine products are drugs. Therefore, CDER should regulate them under the rules governing drug products, including the requirement that FDA approve a new drug application (NDA) before the product may be marketed. Under the regulatory structure for drugs, these products

must necessarily and immediately be removed from the market as adulterated products, as they do not have an approved NDA.

Even if FDA determines that Puff Bar is a tobacco product, it should still be subject to immediate removal from the market. As the manufacturer has indicated, the product has not been reviewed by FDA, nor have any of its marketing statements. Also, by the manufacturer's own admission, it is a "new" product, and was introduced to the market after February 15, 2007. Therefore, it cannot be sold without a market authorization from FDA and must be removed immediately from the market.

In conclusion, we urge FDA to take two actions. First, the agency should immediately demand that Puff Bar products be removed from the market or face enforcement action because, regardless of whether the product is a drug or a tobacco product, it is on the market illegally. Second, FDA should clarify the regulatory status of synthetic nicotine products and make that decision clear to the public, consumers, manufacturers, and retailers. FDA must not allow perceived uncertainty about FDA's position to lead to unfettered access to the market of illegal products, with demonstrably adverse public health consequences to children. Any failure of FDA to act promptly puts our nation's children at risk.

Sincerely,
American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco Free Kids
Parents Against Vaping E-cigarettes
Truth Initiative

CC: Mitch Zeller, Director, Center for Tobacco Products, Food and Drug Administration

Appendices

A: November 6, 2018 Letter to FDA Regarding Regulation of Synthetic Nicotine

B: February 19, 2021 E-mail from Puff Bar to consumers announcing synthetic nicotine products

References

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11. Society for Research on Nicotine and Tobacco Annual Meeting 2021. FDA CTP Director Mitch Zeller's Response to a Question at FDA Special Session on February 24, 2021.

Appendix A



1400 EYE STREET, NW • SUITE 1200 • WASHINGTON, DC 20005
PHONE (202) 296-5469 • FAX (202) 296-5427

November 6, 2018

Dr. Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
White Oak Building One
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Regulation of Synthetic Nicotine

Dear Commissioner Gottlieb:

We write to urge the Food and Drug Administration (FDA) to clarify the regulatory status of products containing synthetic nicotine.

Recent statements from manufacturers of synthetic nicotine – that is, nicotine not derived from tobacco -- reflect their assertion that products containing synthetic nicotine, including e-liquids, are not subject to FDA jurisdiction, presumably because they do not fall within the definition of “tobacco product” under the Food, Drug and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act. FDA should make it clear that products containing synthetic nicotine will be regulated as drugs under the FDCA because they are intended to affect the structure and function of the body. As explained below, this conclusion is supported by (i) the definition of a “drug” in the FDCA, which turns on a product’s “intended use,” (ii) FDA’s long-held view that it can consider “any relevant source of evidence” to determine intended use, and (iii) nicotine’s well-known pharmacological effects that have been exhaustively documented by FDA. Thus, products containing synthetic nicotine must be the subject of an approved new drug application (“NDA”) before they can be commercially marketed.

Background

Statutory Definition of a Drug. Section 505 of the FDCA bars introduction of new drugs into interstate commerce without approval by FDA of an NDA covering the drug. 21 U.S.C. § 505(a). Since no products containing synthetic nicotine are approved and they would not qualify for any exemptions applicable to old products, the critical question is whether these products are drugs, as that term is defined in the statute. The FDCA defines a “drug” in relevant part as (a) an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and (b) an article (other than food) intended to affect the structure or any function of the body. 21 U.S.C. § 321(g)(1)(B)-(C).

Product claims relating to prong (a) are known as “disease claims” or “therapeutic claims.” As FDA has made clear, if the manufacturer or seller of a product makes therapeutic claims, the product will fall within the definition of a drug in the FDCA and thus will require prior approval of an NDA. This bedrock principal applies equally, of course, to products containing nicotine (whether tobacco-derived or synthetic). *E.g.*, Clarification of When Products Made or Derives from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding ‘Intended Uses,’” 82 Fed. Reg. 2193, 2195-96 (Jan. 9, 2017); 21 C.F.R. § 1100.5; *Sottera v. FDA*, 627 F.3d 891 (D.C. Cir. 2010) (FDA has authority to regulate as drugs and/or devices tobacco products that are marketed with therapeutic claims).

Product claims relating to prong (b) are known as “structure/function claims.” There are two components to the definition of these claims: the product must be (i) intended (ii) “to affect the structure or any function of the body.” There should be no dispute that synthetic nicotine satisfies the second component of the structure/function prong. Synthetic nicotine’s effect on functions of the body, like tobacco-derived nicotine, includes satisfaction of addiction, stimulation, sedation, and appetite suppression. “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents,” 61 Fed. Reg. 44418, 44631-44632 (Aug. 28, 1996). Thus, the key question is whether a product containing synthetic nicotine was *intended* to affect a bodily structure or any function.

FDA’s “Intended Use” Regulation. To implement the FDCA’s definition of a drug, FDA has issued a regulation defining “intended use.” 21 C.F.R. § 201.128.¹ That long-standing regulation permits the agency to regulate, as drugs, products based on indicia of “objective intent” of the seller/manufacturer. Under the regulation, FDA may determine intent based on “the circumstances surrounding the distribution of the article” or “the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.” FDA may look to “any relevant source of evidence,” including how consumers use the product. 82 Fed. Reg. 2193, 2206 (Jan. 9, 2017) (citing cases); Regulation of Cigarettes and Smokeless Tobacco under the FDCA, Vol. Two: Final Rule with Juris. Determination, 61 Fed. Reg. 44396, 45163 (Aug. 28, 1996) (“1996 Tobacco Rule”); *Nat’l Nutritional Foods Ass’n v. Matthews*, 557 F.2d 325, 334 (2d Cir. 1977) (FDA can discern a manufacturer’s actual intent “on the basis of objective evidence”).

The Emergence of Synthetic Nicotine Products

Until recently, the nicotine in e-liquids and other nicotine-containing products has been almost exclusively derived from tobacco. As the agency may already be aware, however, firms are now marketing synthetic nicotine to use in such products instead of tobacco-derived nicotine. One firm, Next Generation Labs (“Next Generation”), aggressively promotes its “TFN Nicotine” and touts its use in e-cigarette products and in its own version of nicotine gum. Next Generation claims TFN Nicotine is “tasteless and odorless,” but emphasizes that it still delivers the “*same biological impact as tobacco-derived nicotine*.”² This is powerful evidence that Next Generation, and the manufacturers who incorporate TFN Nicotine into their products, intend TFN Nicotine to

¹ In January 2017, FDA issued a final rule amending this regulation. 82 Fed. Reg. 2193. However, in March 2018 FDA stayed indefinitely the effective date of the amended regulation. 83 Fed. Reg. 11639 (Mar. 16, 2018).

² <https://www.nextgenerationlabs.com/> (emphasis added).

affect the structure or function or the body. Indeed, if the synthetic nicotine is odorless and tasteless, there is no other purpose that it could serve.

Next Generation has announced its use in Space Jam's THE BYRD closed-tank vaping device, as well as in e-liquids like Lost Art Liquids' Strawberry Strike and SQN's NKTR Shake, with Mint, Mango and Strawberry flavors. *See* <https://www.nextgenerationlabs.com/news/>. Each of these e-liquids is available in varying nicotine strengths.

Next Generation has also launched its ZIA brand of 3 mg nicotine gum. While marketing slides state that ZIA is "not intended to assist in quitting efforts," but rather "as a recreational substitute," it also states that it delivers "real nicotine satisfaction." <https://www.nextgenerationlabs.com/zia-gum/> (link to marketing brochure). That same presentation stresses that "You will feel the Nicotine rush very quickly usually within a minute." "Nicotine rush" and "real nicotine satisfaction"—especially when coupled with the statement about TFN Nicotine's "same biological impact"—leave no doubt that Next Generation is promoting the biological effects of nicotine, and that those effects are intended.

Next Generation has not hidden its claim that products containing TFN Nicotine are not subject to any FDA regulation. It issued a press release titled "FDA Confirms TFN Nicotine is Not a Tobacco Product." *See* <https://www.nextgenerationlabs.com/fda-confirms-tfn-nicotine-is-not-a-tobacco-product/>. The press release stated not only Next Generation's position that FDA had acknowledged that products containing synthetic nicotine may not be "tobacco products" under the FDCA, but also the broader claim that TFN Nicotine is "not [] subject to regulation." *Id.*

A Product Containing Synthetic Nicotine Is a Drug under the FDCA.

FDA has acknowledged that an e-cigarette that contains only synthetic nicotine and that will not be used as a component or part of a product that otherwise qualifies as a tobacco product, may fall outside of the FDCA's definition of a "tobacco product," although "FDA intends to make these determinations on a case-by-case basis, based on a totality of the circumstances." Commonly Asked Questions: About the Center for Tobacco Products, available at <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/ucm378205.htm#14>. However, such a product fits squarely within the statute's definition of a "drug" and must be regulated as such.

By adding synthetic nicotine to its product, the manufacturer knows and intends that the product will affect the structure or function of the body—even if it does not overtly communicate that intent by any statement or other action. FDA has previously stated that "the mere presence of a pharmacologically active ingredient could make a product a drug even in the absence of explicit drug claims. In these cases, the intended use would be implied because of the known or recognized drug effects of the ingredient." 59 Fed. Reg. 5226, 5227 (Feb. 3, 1994) (discussing certain over-the-counter vaginal products). That statement applies with full force to e-liquids containing synthetic nicotine: manufacturers know of nicotine's extensively-documented pharmacological effects; know that consumers use nicotine-containing e-liquids to get those effects (like sustaining addiction, mood alteration, and weight control); and add synthetic nicotine to their e-liquids in a range of quantities that produce those effects. FDA must not allow

e-liquid makers to escape agency oversight required by the FDCA and FDA regulations, simply by using synthetic nicotine instead of tobacco-derived nicotine.³

There are many examples where FDA has made jurisdictional determinations about products' regulatory status based on circumstantial evidence, rather than labeling or the manufacturer's statements. Such products include khat (a pharmacologically active shrub known to act as a stimulant when chewed or used as tea), imitation cocaine products, dentifrice products containing fluoride, and any product containing hormones at a level that affects the structure or any function of the body. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 170 (2000); 1996 Tobacco Rule, 61 Fed. Reg. at 45167-68. In the case of products containing TFN Nicotine, the overt public statements by TFN Nicotine's manufacturer—which position its product as a substitute for tobacco-derived nicotine that offers the same biological impact—represents unambiguous evidence that product manufacturers who use TFN Nicotine know and intend that their products will cause those biological effects. 1996 Tobacco Rule, 61 Fed. Reg. at 45168.

In addition, even if the agency were to conclude that the statements made by Next Generation are not effectively adopted by or attributable to the nicotine-containing product's end manufacturer, those manufacturers undoubtedly understand nicotine's pharmacological effects and include nicotine for the sole purpose of causing those effects. Even in the absence of overt structure/function claims, courts have upheld FDA's assertion of jurisdiction over products as drugs in circumstances arguably similar to those presented by synthetic nicotine-containing products. *E.g., United States v. Travia*, 180 F. Supp. 2d 115 (D.D.C. 2001) (holding that nitrous oxide distributed in unlabeled balloons outside of a rock concert was a "drug" because the product was clearly intended to affect the structure or function of the body).

Therefore, the Campaign for Tobacco-Free Kids urges FDA to make it clear that even if the presence of synthetic nicotine does not make a product a "tobacco product" under the FDCA because the nicotine is not "derived from tobacco," products containing synthetic nicotine nevertheless are subject to regulation as "drugs" under the FDCA because they are intended to affect the structure or function of the body. Thank you for your consideration of this important public health issue.

Sincerely,

A handwritten signature in blue ink, reading "Matthew L. Myers".

Matthew L. Myers
President

Cc: Dr. Janet Woodcock, Center for Drug Evaluation and Research
Mitch Zeller, Center for Tobacco Products

³ For additional discussion of why synthetic nicotine-containing products should be regulated as drugs, see Zettler, Patricia J. and Hemmerich, Natalie and Berman, Micah, Closing the Regulatory Gap for Synthetic Nicotine (October 1, 2017). Boston College Law Review, vol. 59, 2018; Georgia State University College of Law, Legal Studies Research Paper No. 2018-03; Ohio State Public Law Working Paper No. 425. Available at SSRN: <https://ssrn.com/abstract=3045317>.

Appendix B

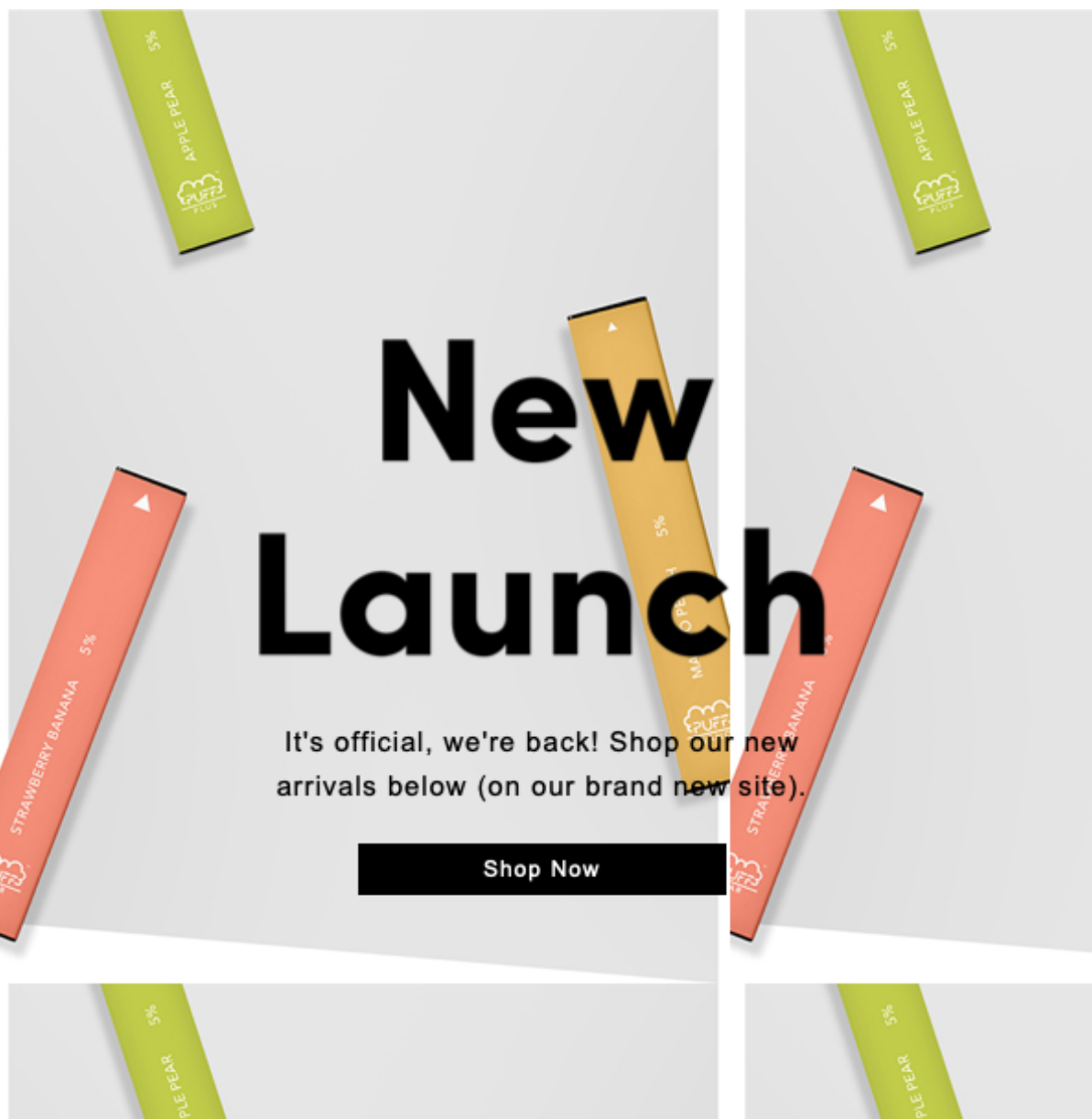
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Date: Wednesday, March 17, 2021 at 5:48:13 PM Eastern Daylight Time
From: Stacey Gagosian
Attachments: image001.png

From: Puff Bar <info@puffbar.com>
Date: February 19, 2021 at 5:04:11 PM EST
To:
Subject: **We're back** fresh launch alert 🌟 just for you...



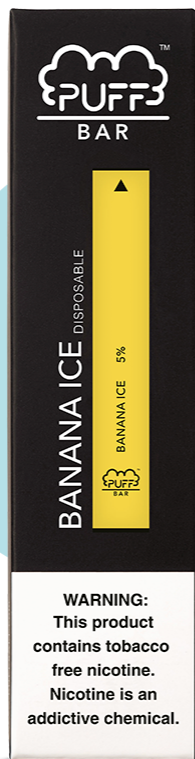
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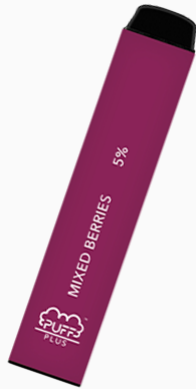
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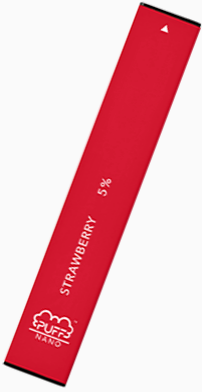


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Puff Bar Nano

		
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Guaranteed
Taste



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Tobacco-Free
Nicotine

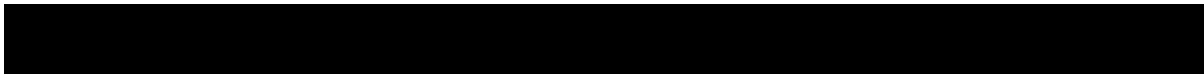
WARNING: This product contains tobacco-free nicotine. Tobacco-free nicotine is an addictive chemical.

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.



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