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July 14, 2020

Mr. Mitchell Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Director Zeller:

We write to bring to your attention a line of "new tobacco products," introduced long after August 8, 2016, without the required marketing authorization from FDA: **Puff Flow e-cigarettes**. Not only do these flavored, disposable e-cigarettes appear to have been released for sale and distribution to U.S. consumers very recently, but their marketing plainly targets young people. Under FDA's current Enforcement Guidance describing its enforcement priorities, first issued in January 2020,[1] FDA should take immediate enforcement action against Puff Flow e-cigarettes to remove them from the market.

Puff Flow e-cigarettes are the latest in a long line of e-cigarettes being introduced to the U.S. marketplace without the required marketing authorization from FDA.[2] Indeed, the manufacturer of Puff Flow e-cigarettes has also likely introduced other disposable e-cigarette products, such as Puff Bar and Puff Bar Plus, after August 8, 2016 without marketing authorization from FDA.[3] While one company that distributes Puff Bar products, including Puff Flow e-cigarettes, announced yesterday that it is suspending

[1] Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised); Guidance for Industry; Availability, 85 Fed. Reg. 23973 (Apr. 30, 2020) (first issued in January 2020 and re-issued in April 2020 "to reflect the court's order in *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, Case No. 8:18-cv-883 (PWG), (D. Md. Apr. 22, 2020), Dkt. No. 182, granting a motion for a 120-day extension (until September 9, 2020) in light of the global outbreak of respiratory illness caused by a new coronavirus).

[2] *See e.g.,* Public health groups' letter to FDA, dated August 7, 2018, detailing the "alarming pace in total defiance of the law" of e-cigarettes being introduced to the market after the Deeming Rule's effective date and urging FDA "to take quick and aggressive action to enforce the law before one or more of these products becomes the next Juul phenomenon among our nation's youth." Available at https://www.tobaccofreekids.org/what-we-do/us/fda/comments-letters (last visited July 10, 2020).

[3] *See e.g.,* Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to then FDA Commissioner, Dr. Stephen Hahn, Mar. 6, 2020, https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-03-06.RK%20to%20Hahn-FDA%20re%20E-Cig%20Exemptions.pdf (last visited July 10, 2020).

U.S. sales "until further notice,"[4] FDA enforcement action is necessary to ensure the decision to begin selling again is not left to the company. FDA should promptly investigate all Puff Bar products as well and take enforcement action against manufacturers, distributors, and retailers as necessary.

In addition to taking enforcement action against Puff Flow and related products, FDA should end the current exemption of disposable e-cigarettes from its prioritized enforcement against certain flavored e-cigarette products. This exemption has led to increased sales of disposables, along with the blatant targeting of youth by both Puff Flow and other flavored, disposable e-cigarette brands.

It is important that FDA recognize the urgency of using the full force of its regulatory authority as quickly as possible. The delay of statutorily-required premarket review has allowed a seemingly never-ending plethora of new products onto the market without FDA playing the gatekeeping role Congress envisioned.[5] One of the major consequences of this years-long delay is the explosion of youth e-cigarette use, which both the FDA and U.S. Surgeon General have declared an "epidemic."[6] Without swift and forceful enforcement actions against companies flagrantly violating the law, and rigorous premarket review authorizing only those "new tobacco products" that meet the statute's strict requirements to be sold in the first place, the youth e-cigarette epidemic and its potentially deadly consequences for subsequent life-long tobacco use may be one genie that can never be put back in the bottle.

Puff Flow e-cigarettes appear to be "new tobacco products," introduced long after August 8, 2016, without the required FDA marketing authorization

Under the Deeming Rule, effective August 8, 2016, e-cigarettes and other newly deemed tobacco products that meet the Family Smoking Prevention and Tobacco Control Act's definition of "new tobacco product" are required to have premarket authorization.[7] A "new tobacco product" is any tobacco product not commercially marketed in the U.S. as of February 15, 2007 or any tobacco product modified after that date.[8] While newly deemed tobacco products *already on the market as of August 8, 2016* are subject to FDA's Compliance Policy deferring enforcement of required premarket review, the Deeming Rule prohibited "new tobacco products" from being introduced *after August 8, 2016* unless they first undergo premarket review and receive a marketing authorization.[9] "New tobacco products"

[4] Eli Wolfe, *Controversial E-Cigarette Company Puff Bar Says It's Suspending U.S. Sales*, FAIR WARNING, July 13, 2020. Available at https://bit.ly/3j4SvW6 (last visited July 14, 2020).
[5] Public health groups' letter to FDA, *supra* note 2.
[6] FDA, "Think E-Cigs Can't Harm Teens' Health?," Apr. 30, 2018, https://www.fda.gov/tobacco-products/public-health-education/think-e-cigs-cant-harm-teens-health (last visited July 9, 2020); Office of the Surgeon General, "Surgeon General's Advisory on E-Cigarette Use Among Youth," Dec. 18, 2018, https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf (last visited July 9, 2020).
[7] Final Rule, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016) (relevant sections codified at 21 C.F.R. pt. 1100).
[8] 21 U.S.C. §387j(a)(1).
[9] Deeming Rule, *supra* note 7, at 29,011. *See also* Enforcement Guidance, *supra* note 1, at 4-5.

introduced after that date without marketing authorization are "adulterated products" under the Federal Food, Drug, and Cosmetic Act.[10]

Puff Flow e-cigarettes are "new tobacco products" because they were not commercially marketed in the U.S. as of February 15, 2007 (the "grandfather date"). In fact, they appear to have been introduced or modified long after the Deeming Rule's effective date of August 8, 2016. The earliest social media posts for these products appeared in early to mid-June 2020, and video reviews of the product did not appear on YouTube until late June 2020.[11] The attached slide deck provides numerous examples of Puff Flow being marketed and "introduced" as "new," "the first of its kind … disposable that has adjustable air flow," and in "all new flavors" by various retailers and e-cigarette reviewers.[12]

The product's new flavors, and a "switch" that allows a change in airflow, are features that could have adverse effects on individual users' health and to the health of the population as a whole. Plainly, these are significant changes in the characteristics of the product, not simply changes in name from products on the market on the grandfather date.[13] There simply is no question that Puff Flow e-cigarettes are "new tobacco products" that must be authorized by FDA before being sold or distributed to U.S. consumers.

Because Puff Flow e-cigarettes were introduced or modified after August 8, 2016, they cannot receive the benefit of FDA's Compliance Policy. To the best of our knowledge, no marketing authorization orders have been issued for Puff Flow e-cigarettes. They are, therefore, adulterated products that are on the market illegally. Thus, FDA should move expeditiously to bring an enforcement action against, and remove from the market, these illegally marketed products.

Puff Flow e-cigarettes are designed and marketed to be appealing to young people, encouraging their use by minors

FDA's Enforcement Guidance, first issued in January 2020, prioritizes enforcement against any e-cigarette product "that is targeted to minors or whose marketing is likely to promote the use of ENDS by minors."[14] The current marketing of Puff Flow e-cigarettes is transparently designed to make these products appealing to young people. In one video review of the product identified in the attached slides (ChaseSmokes' Review), the users are clearly young.[15] The youthful ChaseSmokes' Review had more than 10,000 views at the time of this letter's writing, representing more than three times the viewership of the second most watched video review of Puff Flow by an older adult.[16] It is even more concerning that one commenter of the ChaseSmokes' Review wrote, "We all know that some of us are still watching under the age of 21."[17]

[10] 21 U.S.C. §387b(6)(A).
[11] Dated examples are provided in the attached slides.
[12] Slides 3-8; 15.
[13] *Philip Morris USA Inc. v. FDA*, 202 F.Supp.3d 31, 36 (D.D.C. 2016) (holding that changes to a product's label, including a name change, does not result in a "new tobacco product").
[14] *Supra* note 1, at 3 (noting that "minor" refers to individuals under age 21).
[15] Slide 14.
[16] Slides 14-15.
[17] Slide 14.

Puff Flow e-cigarettes have many of the same features that have made JUUL e-cigarettes wildly popular among young people. They come in an array of youth-appealing flavors, look sleek, can be easily concealed, are promoted as easy to use, and contain the same high nicotine salt concentration as JUUL.[18] A preliminary finding from a study conducted in early May 2020 using nationally representative data found that among adolescents (13-17 years old), past 30-day use of Puff Bar and other newer disposables is higher than JUUL.[19] Thus, if the popularity of Puff Bar, from the same manufacturer as Puff Flow, is any indication, rampant use of Puff Flow e-cigarettes by young people is likely to become a reality. Because Puff Flow is being marketed to young people, FDA enforcement action is imperative under the current Enforcement Guidance.[20]

FDA should end its enforcement exemption for flavored, disposable e-cigarettes

Finally, in addition to commencing an enforcement action to remove Puff Flow e-cigarettes and other related products from the market, FDA should acknowledge that its current Enforcement Guidance has significant limitations, making it a wholly inadequate response to the skyrocketing youth use of e-cigarettes. The agency's inexplicable exemption of disposable products from its flavored e-cigarette prioritized enforcement policy is one such limitation, with real and present adverse effects on public health.

The exemption is fueling growing sales of disposable e-cigarette products. A May 2020 industry analyst report noted, "We expect brands in the disposable e-cig segment to continue to gain share as long as they are not covered by the FDA's restriction on non-tobacco/non-menthol flavor variants."[21] A more recent report using Nielsen data concluded that the "e-cig refill market," which includes those products prioritized for enforcement by FDA's January 2020 policy, continues to contract while the "e-cig disposable market … has thrived as it falls outside the FDA's flavor ban."[22] The disposable e-cigarette loophole is not just a Puff Flow problem, but a category-wide problem as well.

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[18] *See e.g.*, all of the attached slides, which include URLs to video reviews of the product.

[19] Bonnie Halpern-Felsher, preliminary data (forthcoming) (communication on file with author).

[20] FDA should also commence enforcement actions against retailers selling Puff Flow and other noncomplying products. FDA has issued numerous warning letters *to* retailers for offering for sale tobacco products that require, and do not have, marketing authorization from FDA since implementing its new enforcement priorities. FDA, "Enforcement Actions Against Illegally Marketed Tobacco Products," Apr. 27, 2020, https://www.fda.gov/tobacco-products/ctp-newsroom/enforcement-actions-against-illegally-marketed-tobacco-products (last visited July 9, 2020). In an announcement describing the first of these letters, FDA stated, "Retailers and distributors are encouraged to communicate with their suppliers to discuss possible options for the unauthorized products in their inventory." FDA News Release, "FDA Warns Retailers, Manufacturers to Remove Unauthorized E-Cigarette Products from Market: Agency Continues to Conduct Inspections to Ensure Compliance with Focus on Targeted Unauthorized Flavored E-Cigarette Products Appealing to Youth," Mar. 10, 2020, https://www.fda.gov/news-events/press-announcements/fda-warns-retailers-manufacturers-remove-unauthorized-e-cigarette-products-market (last visited July 9, 2020).

[21] Bonnie Herzog et al., *Americas Tobacco: Nielsen Data Through 5/16 - Cig Consumption Increases as Cig Vol Declines Continue to Moderate*, GOLDMAN SACHS EQUITY RESEARCH, May 26, 2020, at 2.

[22] Bonnie Herzog et al., *Americas Tobacco: Nielsen Data Through 6/13 - Nicotine Sales Pick Up As Cig/Smokeless Vols Improve*, GOLDMAN SACHS EQUITY RESEARCH, June 23, 2020, at 2. Note that Nielsen only tracks traditional retailers such as mass channel and convenience stores, not online sales or sales from tobacco and vape shops, which make up a considerable part of overall e-cigarette sales

Still, industry analyst reports document the trend of increasing dollar share for Puff Bar specifically. Through mid-June, Nielsen data show that Puff Bar's 52-week dollar sales reached above $26M, after having minimal market presence before January 2020.[23] This led to the analysts declaring Puff Bar as one of the "biggest winners in disposables," with 4-week sales data showing it as the leading disposable brand, making up 35.1% of retail dollar sales, ahead of major companies' products blu and NJOY.[24] Of greatest concern, as noted previously, is the growing popularity of Puff Bar among young people.

There is no legal or public health justification for Puff Flow e-cigarettes to remain on the market. FDA should take action against these products and should end the enforcement exemption that has allowed it, and flavored, disposable e-cigarette products like it, to continue to addict our young people.

Thank you for your consideration,

Matthew L. Myers, President
Campaign for Tobacco-Free Kids

cc: Ms. Ann Simoneau, Director, Office of Compliance and Enforcement, Center for Tobacco Products

[23] Bonnie Herzog et al., *Americas Tobacco: Nielsen Data Through 5/30 - Nicotine Sales Pick Up As Cig/Smokeless Volumes Improve*, GOLDMAN SACHS EQUITY RESEARCH, June 9, 2020, at 2.
[24] Bonnie Herzog et al., *supra* note 21, at 2; 11.