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September 24, 2021

Dr. Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD. 20993

RE: Immediate Need for FDA Decisions Denying PMTAs for Flavored E-Cigarettes

Dear Dr. Woodcock:

In your statement of September 9 on FDA’s public health review of new tobacco products, you properly recognized the “public health threat posed by the well-documented, alarming levels of youth use” of flavored e-cigarette products and reported that the agency has denied marketing orders for more than 946,000 of such products.¹ While this action represents a positive first step in moving against the flavored products that are addicting our kids, we write to express our deep concern that FDA continues to allow the marketing of the flavored e-cigarette and e-liquid products that have been primarily responsible for fueling the youth e-cigarette epidemic.

We urge FDA to expedite decisions on Premarket Tobacco Product Applications (PMTAs) submitted for all non-tobacco flavored e-cigarette products,² and promptly deny those applications, including those for menthol-flavored products, based on the accumulated scientific evidence of the adverse impact of those products on public health. To our knowledge, FDA has not exempted any products, including tobacco-flavored products, from premarket review requirements “for good cause on a case-by-case basis.” as required by the federal court order

¹ Statement of Janet Woodcock, M.D., *FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 million ‘Deemed’ New Tobacco Products Submitted*, at 1 (Sept. 9, 2021), <https://www.fda.gov/news-events/press-announcements/fda-makes-significant-progress-science-based-public-health-application-review-taking-action-over-90> (Woodcock Statement). FDA subsequently announced that it had issued additional MDOs and that MDOs had been issued for a total of over 1,167,000 flavored products.

² According to FDA, the available data suggest that “tobacco-flavored [e-cigarette] products, unlike products with other characterizing flavors, are used by relatively few youth.” FDA, *Perspective: FDA’s Progress on Tobacco Product Application Review and Related Enforcement*, at 7 (Sept. 9, 2021), <https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-tobacco-product-application-review-and-related-enforcement/>.

discussed below. We urge FDA to prioritize enforcement of the statutory premarket authorization requirement against the flavored products with the highest market shares and the products with the highest prevalence of youth usage. Finally, we urge greater transparency about the products that have been the subject of Marketing Denial Orders (MDOs).

As you are aware, FDA is operating under the terms of a federal court order, entered by Judge Paul Grimm of the U.S. District Court for the District of Maryland in *Am. Academy of Pediatrics (AAP) v. FDA*, 379 F. Supp. 3d 461 (D. Md. 2019); 399 F. Supp. 3d 479 (D. Md. 2019), *appeal dismissed sub nom. In re Cigar Ass'n of America*, 812 F. App'x 128 (4th Cir. 2020), intended to remedy the agency's past unlawful suspension of the premarket review process for new tobacco products. Under that order, PMTAs for new tobacco products on the market as of the effective date of the deeming rule were required to be filed by a date certain (extended by subsequent order to September 9, 2020). *AAP*, 399 F. Supp. 3d at 487. Products with applications timely filed were allowed to "remain on the market without being subject to FDA enforcement actions for a period *not to exceed one year* from the date of application while FDA considers the application," a period that expired on September 9 of this year. *Id.* (emphasis added). In contrast to the one-year limit on the enforcement safe harbor during FDA review in Judge Grimm's order, the 2017 Guidance vacated by his decision had extended that safe harbor until FDA reached a decision on the application.³

This court order was intended to end the years-long regulatory "holiday" (the court's term) enjoyed by new tobacco products during which their products were allowed to stay on the market without the marketing authorization required by statute.⁴ The court found a direct connection between FDA's suspension of the marketing authorization requirement and the e-cigarette epidemic among youth, finding that the agency had allowed manufacturers to "continue to advertise and sell products that are addictive and that target a youth market" *AAP*, 379 F. Supp. 3d at 492. As explained in more detail below, because of FDA's failure to take sufficient action on or before September 9 against flavored e-cigarette products, companies are able to continue to advertise and sell the flavored products responsible for the youth e-cigarette epidemic without marketing orders for an indeterminate period into the future. This is exactly the result Judge Grimm sought to prevent.

First, although FDA has said it has resolved 93% of the PMTAs that were timely filed,⁵ it has not issued PMTA decisions for any of the products constituting a high percentage of the e-cigarette market. According to Nielsen's August 2021 analysis of convenience store data, the top four e-cigarette brands (Juul, Vuse, NJOY, and Blu) make up over 78% of the market,⁶ yet

³ In his opinion vacating the 2017 FDA Guidance, Judge Grimm took note that, under that Guidance, there would be a "continued compliance period" pending FDA review of the applications which "will continue *until the agency renders a decision on an application.*" *AAP*, 379 F. Supp. 3d at 472 (citation omitted, emphasis in original).

⁴ FDA's 2017 Guidance afforded "those manufacturers responsible for the public harm a holiday from meeting the obligations of the law." *AAP*, 379 F. Supp. 3d at 493.

⁵ Woodcock Statement, at 1.

⁶ Richard Craver, *Market share for top-selling Juul remains on decline in convenience stores*, WINSTON-SALEM JOURNAL (Aug. 27, 2021), https://journalnow.com/business/local/market-share-for-top-selling-juul-remains-on-decline-in-convenience-stores/article_ee364310-05a3-11ec-a08a-b7513507c946.html (Juul comprised 41.1% of this market, Vuse 31.2%, NJOY 3.7%, and Blu 2.5%).

FDA has not issued a single PMTA decision for any of these brands' products, despite the agency's stated intention to identify and ensure "first review" of the applications for products "that account for most of the current market."⁷ According to FDA, prioritizing these products would assure "the greatest public health impact most quickly."⁸ FDA has offered no explanation for its failure to complete review of the products it has acknowledged are having the greatest impact on public health.

Second, FDA has failed to issue PMTA decisions for at least two-thirds of the products that high school e-cigarette users report as their usual brand, including such brands as Juul, NJOY, SMOK, Suorin and Vuse.⁹ All of these products come in flavors, or can be used with flavors, that clearly appeal to young people.

Third, in your statement of September 9, you explained that FDA's "highest enforcement priorities" include products that remain on the market despite receiving MDOs or failing to submit PMTAs.¹⁰ This statement suggests that the agency is *not* prioritizing enforcement against products that remain on the market after September 9 despite receiving no decision from FDA on their PMTAs. *This indicates that FDA is not prioritizing enforcement against any of the products with the greatest market share or any of the products most used by youth.* In effect, this grants these products a new "safe harbor" against FDA enforcement until the agency rules on their PMTAs – the result Judge Grimm rejected when he limited to one year the period during which companies could keep their products on the market without a marketing order and be insulated from FDA enforcement.

In effect, FDA is placing the burden of its own delay in completing PMTA review of these flavored products on their young victims, who suffer from the continued market presence of these products, instead of on the companies that are causing the continuing epidemic of youth nicotine addiction. This is unacceptable to the public health community.

Finally, FDA has failed to be transparent about the products for which it has issued MDOs. To ensure against the continued availability of e-cigarette products that FDA has found unable to satisfy the statutory public health standard, and to enable the public to assess FDA's enforcement against those products, FDA should disclose the products, and their flavors, for which MDOs have been issued and should continue to publicly identify those products going forward.

Of particular concern is FDA's failure to identify any menthol-flavored products for which MDOs have been issued. Contrary to FDA's August 26 statement that menthol e-cigarette

⁷ Mitch Zeller, *Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline* (Feb. 16, 2021), <https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline>.

⁸ *Id.*

⁹ See Teresa W. Wang, et al., *Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020*, JAMA NETWORK OPEN (published online June 7, 2021), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780705>.

¹⁰ Woodcock Statement, at 2.

products raise “unique considerations” for purposes of FDA review,¹¹ we do not believe there is anything “unique” about menthol flavoring that would justify issuance of a marketing order. Indeed, there is no question that when FDA decided to prioritize enforcement against cartridge-based e-cigarettes in flavors other than menthol and tobacco, youth shifted to using menthol-flavored products. According to the latest data, over one million youth use menthol-flavored e-cigarettes.¹² In 2020, 37% of high school users of flavored e-cigarettes, including 45% of users of flavored refillable cartridge systems like JUUL, reported using menthol products.¹³ It is critical that FDA issue MDOs for menthol-flavored products and that it make the public aware of its decisions on such products.¹⁴

Therefore, we urge FDA to take several concrete actions to remedy the deficiencies in its public health review of e-cigarettes:

- (1) complete review of all e-cigarette products without further delay;
- (2) issue MDOs for non-tobacco flavored products, including menthol-flavored products, based on the continuing adverse impact of those products on public health, and particularly their impact on youth;
- (3) immediately revise the enforcement policy announced on September 9 to include prioritized enforcement against e-cigarette products that continue to be sold without marketing authorization if they are (a) flavored products with the highest market shares or (b) products with the highest prevalence of youth usage; and
- (4) identify, on an on-going basis, the products, and their flavors, that receive MDOs, including all menthol-flavored products.

Thank you for your consideration of our views.

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 (PAVe)
Truth Initiative

CC: Mitch Zeller, Director, FDA Center for Tobacco Products

¹¹ FDA News Release, *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence they Appropriately Protect Public Health*, at 3 (Aug. 26, 2021), <https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence>.

¹² Wang, *supra* note 9.

¹³ *Id.*

¹⁴ We note reporting that suggests FDA may have issued MDOs for some menthol-flavored e-cigarette products. We urge the agency to clarify whether such decisions have been made and, if MDOs have been issued, to ensure that those products are no longer being marketed. Alex Norcia, *Major Disposable Vape Maker Disputes FDA's Marketing Denial Order*, FILTER (Sept. 16, 2021), <https://filtermag.org/bidi-vape-menthol-fda/>.