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Via ECF

Hon. Paul W. Grimm
United States District Judge
U.S. District Court for the District of Maryland

Re: *American Academy of Pediatrics v. FDA*, No. 8:18-cv-883-PWG

Dear Judge Grimm:

In accordance with the Court's November 30, 2021 order, Defendants submit this response to Plaintiffs' letter requesting that the case be reopened and that the FDA be ordered to file regular status reports (ECF No. 195). Defendants respectfully submit that regular status reports are not warranted at this time. The FDA has implemented the remedy ordered by the Court and has made substantial progress in reviewing an unprecedented number of premarket applications — which has spawned ongoing litigation throughout the courts of appeals — and initiated regulatory efforts targeting millions of products without premarket authorization.

The Tobacco Control Act authorized the FDA to regulate cigarettes and smokeless tobacco and to deem other tobacco products subject to the Act's requirements. 21 U.S.C. § 387a(b). The Act also made it unlawful to market new tobacco products without FDA authorization. *Id.* § 387j(a)(2). This case challenged 2017 guidance announcing a compliance policy under which certain newly deemed tobacco products were expected to "remain on the market without submitting a premarket application to the FDA" for four to five years and to "remain on the market while their application is pending." *Am. Acad. of Pediatrics (AAP) v. FDA*, 379 F. Supp. 3d 461, 468 (D. Md. 2019) (citation omitted). This Court vacated the 2017 guidance, *id.* at 498, and set a September 9, 2020 filing deadline for premarket applications for newly deemed tobacco products on the market when the deeming rule took effect. *AAP v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019); ECF No. 182. Under the remedial order, newly deemed tobacco products without timely applications were subject to enforcement actions in the FDA's discretion. 399 F. Supp. 3d at 487. Newly deemed tobacco products with timely applications could generally remain on the market for up to a year pending FDA review. *Id.* Finally, the Court retained jurisdiction over the case but found no "present need to require court monitoring through quarterly status reports" in light of the FDA's proposed approach and timetable. *Id.*

The FDA received premarket applications for over 6.5 million tobacco products by the September 2020 deadline. *See* FDA, *Perspective: FDA's Progress on Tobacco Product Application Review and Related Enforcement* (*Sept. 2021 Progress Perspective*), *available at* https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-tobacco-product-application-review-and-related-enforcement (Sept. 9, 2021). To review this large number of submissions as efficiently and fairly as possible, the FDA developed a structured review process. FDA, *Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline* (*Feb. 2021 Progress Perspective*), *available*

at https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline (Feb. 16, 2021).

The FDA has made considerable headway in reviewing the applications it received, and it has consistently updated the industry and public about its progress. As of September 2021, the FDA has completed the acceptance review — the first phase in the agency's three-phase review process — for all submissions received by the September 2020 deadline. *See Sept. 2021 Progress Perspective*. The acceptance review entails determining whether the product falls under the jurisdiction of the FDA's Center for Tobacco Products and whether the application meets certain basic requirements, like being in an accessible electronic format and including an environmental assessment. *See Feb. 2021 Progress Perspective*. The FDA accepted the applications for over 6.5 million products and refused to accept the applications for over 200,000 products that did not meet the basic application requirements. *See Sept. 2021 Progress Perspective*.

The FDA has also completed the filing review — the second phase — for about 90% of the timely submissions as of September 2021. *See id.* The filing review entails determining whether the application contains all of the items required by statute or regulation, like ingredient listings, labels for each product to be marketed, and adequate environmental assessments. *See Feb. 2021 Progress Perspective*. As part of this filing review, the agency refused to file the applications for over 5 million products. *See* FDA, *PMTA Acceptance Phase Metrics* (*PMTA Metrics*), *available at* https://www.fda.gov/media/154053/download (last updated Oct. 6, 2021).

Finally, the FDA has completed the substantive review — the third phase — for over 1.1 million flavored e-cigarette products. *See PMTA Metrics*. The substantive review is the longest and most thorough phase and entails evaluating the application's scientific information and data. *See Feb. 2021 Progress Perspective*. To date, the FDA's substantive review has resulted in substantial equivalence marketing orders for over 120 products (*see* 21 U.S.C. § 387j(a)(2)(A)(i)), exemption from substantial equivalence orders for over 230 products (*see id.* § 387j(a)(2)(A)(ii)), and premarket tobacco product marketing granted orders for 3 products (*see id.* § 387j(c)(1)(A)). *See Sept. 2021 Progress Perspective*; FDA, *Premarket Tobacco Product Marketing Granted Orders*, *available at* https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders (last updated Oct. 25, 2021). The FDA has also issued over 300 marketing denial orders for over 1.1 million flavored e-cigarette products whose applications lacked sufficient evidence to demonstrate that allowing the products to be marketed would be appropriate for the protection of the public health. *See* FDA, *FDA In Brief: FDA Warns Firms for Continuing to Market E-cigarette Products After Agency Denied Authorizations* (*FDA In Brief*), *available at* https://www.fda.gov/news-events/press-announcements/fda-brief-fda-warns-firms-continuing-market-e-cigarette-products-after-agency-denied-authorizations (Oct. 7, 2021).

All told, the FDA has resolved about 98% of the timely premarket applications. *See* FDA, *FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency*, *available at* https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency (Oct. 12, 2021). The agency is continuing to devote significant resources to expeditiously resolve the remaining pending applications and plans to issue further decisions on a rolling basis. *See id.*

In addition to this progress in reviewing applications, the FDA has also been defending dozens of challenges to the agency's application denials. Since September 2021, 48 such cases have

been filed in the courts of appeals, which have exclusive jurisdiction over petitions for review of orders denying premarket tobacco applications, *see* 21 U.S.C. § 387*l*(a)(1)(B) — including 8 in the Fourth Circuit alone, *see, e.g.*, *Avail Vapor v. FDA*, No. 21-2077 (4th Cir.). Some manufacturers have also sought stays of their marketing denial orders pending review, which were granted by the Fifth and Seventh Circuits, *Wages & White Lion Invs., L.L.C., d/b/a Triton Distrib. v. FDA*, 16 F.4th 1130 (5th Cir. 2021); Order, *Gripum LLC v. FDA*, No. 21-2840 (7th Cir. Nov. 4, 2021), but denied by the Sixth Circuit, *Breeze Smoke, LLC v. FDA*, --- F.4th ---, No. 21-3902, 2021 WL 5276303 (6th Cir. Nov. 12, 2021), *emergency application for stay denied*, No. 21A176 (S. Ct. Dec. 10, 2021). In response to these challenges, the FDA has rescinded several denial orders and has agreed to re-review other applications whose manufacturers alleged certain errors in the review process. These re-reviews are ongoing.

In the meantime, the FDA has also initiated regulatory efforts directed toward millions of newly deemed tobacco products without premarket authorization — consistent with the enforcement priorities it announced in January 2020. *See* FDA, *Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* (*2020 Guidance*), *available at* https://www.fda.gov/media/133880/download (Apr. 2020). From January 2021 through September 2021, the agency issued over 170 warning letters to firms that have over 17 million e-cigarette products listed with the FDA and that had not submitted timely premarket applications for these products. *See* FDA, *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* (*Progress Release*), *available at* https://www.fda.gov/news-events/press-announcements/fda-makes-significant-progress-science-based-public-health-application-review-taking-action-over-90 (Sept. 9, 2021). These warning letters include a letter to a company with over 15 million products listed with the FDA that did not submit an application. *See id.* As of October 7, 2021, the FDA has also issued warning letters to 20 companies that received marketing denial orders. *See FDA In Brief*.

Given the FDA's full implementation of the Court's remedy order, its substantial and continuing progress in reviewing the unprecedented volume of applications, the ongoing litigation over that review throughout the courts of appeals, and the agency's regulatory efforts against products without premarket authorization, Plaintiffs' request for regular status reports is not merited at this time. Indeed, Plaintiffs do not dispute that the agency is using considerable resources to review applications and initiate regulatory efforts against products without premarket authorization. Instead, Plaintiffs' two complaints boil down to disagreements about how the agency should prioritize those limited resources — (a) whether to determine application review order based solely on market share (Plaintiffs' preference, *see* Pls.' Ltr. at 2–3) or instead based on multiple considerations, including an element of randomization so as to give both small and large companies a chance to have applications reviewed earlier in the process (the FDA's choice, *see Feb. 2021 Progress Perspective*); and (b) whether to prioritize enforcement efforts against manufacturers with pending applications (Plaintiffs' preference, *see* Pls.' Ltr. at 3) or instead against manufacturers without pending applications, like those who flouted their obligation to submit applications by September 2020 (the FDA's choice, *see Progress Release*). While Plaintiffs may disagree with the FDA's priorities, the agency's choices here are a far cry from the "'wholesale suspension' of the application filing and approval requirements" for which the Court invalidated the 2017 guidance. 379 F. Supp. 3d at 485 (citation omitted). Plaintiffs' request should thus be denied without prejudice.

We thank the Court for its attention to this matter.

Respectfully submitted,

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