No. 23-1038

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, PETITIONER
v.
WAGES AND WHITE LION INVESTMENTS, L.L.C.,
DBA TRITON DISTRIBUTION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF OF LOGIC TECHNOLOGY DEVELOPMENT LLC AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION

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QUESTION PRESENTED

Whether the Food and Drug Administration's creation of a new, heightened standard for evaluating already-pending premarket tobacco product applications for certain electronic nicotine delivery systems products was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

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INTEREST OF *AMICUS CURIAE*[1]

Amicus Logic Technology Development LLC imports and sells electronic nicotine delivery systems ("ENDS"), featuring a rechargeable battery-operated device used with cartridges of e-liquid. *Amicus* has sold its ENDS devices—the Logic Vapeleaf, Logic Power, and Logic Pro—lawfully in the United States for over a decade. These products offer a viable, safer alternative to combustible cigarettes, and can assist adults seeking to transition away from combustibles.

In 2019, *Amicus* submitted premarket tobacco product applications ("PMTAs") to the Food and Drug Administration ("FDA") seeking marketing authorization for multiple different ENDS products in fruit, menthol, and tobacco flavors. *Amicus* invested tens of millions of dollars to prepare its PMTAs, including for its menthol-flavored ENDS products. *Amicus* hired dozens of professionals, contracted with several scientific research companies, and met with FDA to discuss and plan the content of its PMTAs,

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[1] Pursuant to this Court's Rule 37.2, *Amicus* provided timely notice to all parties of its intent to file this *amicus* brief. Further, pursuant to this Court's Rule 37.6, *Amicus* states that no counsel for any party authored this brief in whole or in part, and that no entity or person, aside from *Amicus* or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

including clinical and nonclinical studies. *Amicus*' PMTAs showed that its products benefit current adult smokers and are not used by youth in any appreciable amounts. In fact, the evidence supporting *Amicus*' menthol-flavored ENDS applications was so robust that the FDA's Center for Tobacco Products' Office of Science recommended granting marketing authorization for these products before FDA's new political leadership reversed course. As *Amicus* would only later learn, FDA's leadership decided to extend to menthol-flavored PMTAs the same heightened, vague evidentiary standard that the agency had initially crafted to justify its *en masse* denial of fruit-, candy-, and dessert-flavored ENDS PMTAs. Applying this heightened standard, FDA issued a Marketing Denial Order ("MDO") for *Amicus*' menthol-flavored ENDS products.

Amicus files this brief to explain that if this Court grants the present Petition, it should also grant review in *Amicus*' pending petition. *See* Pet. for Writ of Cert., *Logic Tech. Dev. LLC v. FDA*, No.23-1125 (filed Apr. 15, 2024). *Amicus*' pending petition raises the Question Presented here—whether FDA violated the Administrative Procedure Act ("APA") by applying a new, heightened standard for evaluating already-pending PMTAs for fruit-, candy-, and dessert-flavored ENDS—as well as the closely related but distinct Question Presented of whether FDA's subsequent, retroactive extension of its heightened evidentiary standard to pending PMTAs for menthol-flavored ENDS was also "arbitrary, capricious, an

abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

Amicus' case also differs from the present Petition in important respects that make it an ideal companion. FDA specifically led *Amicus* to believe that the agency's new, heightened evidentiary standard would not apply to menthol-flavored ENDS PMTAs. But then FDA reversed its position in secret, extending its new evidentiary standard to menthol-flavored ENDS. Further, FDA's career expert staff had unanimously recommended granting marketing authorization to *Amicus*' menthol-flavored ENDS based upon *Amicus*' robust evidentiary submission demonstrating these products' benefits for adults and lack of appeal to youth. But then, as revealed in two extraordinary internal memoranda, FDA's new political leadership overruled the agency's career experts and retroactively imposed the new evidentiary standard on *Amicus*' menthol-flavored ENDS in order to deny marketing authorization.

INTRODUCTION AND SUMMARY OF ARGUMENT

Companies sell ENDS, or e-cigarettes, in different flavors, including tobacco, menthol, fruit, candy, and dessert. Tobacco- and menthol-flavored ENDS are particularly important to public health, as they offer a critical resource for adult smokers that want to switch from combustible cigarettes. Menthol-flavored cigarettes comprise roughly 37% of all cigarette sales

in the United States, with tobacco-flavored cigarette sales making up the rest. *See Menthol Tobacco Products*, CDC (Aug. 23, 2023).[2] As Former FDA Commissioner Scott Gottlieb correctly explained, menthol-flavored ENDS, in particular, "may be important to adult smokers looking to transition away from cigarettes," given that "combustible cigarettes are still sold in menthol flavor." *See* Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Proposed New Steps to Protect Youth (Nov. 15, 2018) (hereinafter "Statement from Commissioner Gottlieb").[3] Fruit-, candy-, and dessert-flavored ENDS, on the other hand, have no analogue in lawfully sold cigarettes.

FDA implemented a two-step strategy to ensure that no non-tobacco-flavored ENDS product would receive marketing authorization. First, FDA targeted PMTAs for fruit-, candy-, and dessert-flavored ENDS. Despite telling ENDS companies that they would not need to submit long-term studies, FDA denied every fruit-, candy-, or dessert-flavored ENDS PMTA that failed to include a certain type of study, based upon a retroactive policy decision to ban all such ENDS. In particular, the agency required studies showing that

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[2] Available at https://www.cdc.gov/tobacco/basic_information/menthol/index.html (all websites last visited Apr. 17, 2024).

[3] Available at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access.

an applicant's fruit-, candy-, or dessert-flavored ENDS were more effective than tobacco-flavored ENDS, to some unspecified degree, in helping current smokers reduce or quit smoking. This new, amorphous standard allowed FDA to deny *en masse* all PMTAs for these products. Second, and as revealed in two memoranda disclosed for the first time in connection with *Amicus*' PMTAs, FDA extended, without notice or any record support, the same unlawful, heightened evidentiary burden to menthol-flavored ENDS PMTAs that it had devised for fruit-, candy-, and dessert-flavored ENDS applications. FDA then proceeded to deny every menthol-flavored ENDS PMTA that it considered, starting first with *Amicus*' PMTAs.

The present Petition raises only the legality of the first step of this two-step strategy, and *Amicus* respectfully submits that for this Court to evaluate properly FDA's anti-ENDS campaign, it should grant *Amicus*' pending petition as a companion to the present Petition for several reasons. First, there are distinct circuit splits on both steps of FDA's unlawful anti-ENDS scheme, and this Court should consider both of these closely related but distinct issues together. Second, FDA's effort to impose retroactively a heightened evidentiary standard for already-pending PMTAs is most practically consequential and legally indefensible when applied to menthol products, which offer a valuable resource for current menthol smokers seeking to transition away from combustibles. Finally, if FDA is going to come before

this Court to defend the legality of its effort to outlaw the majority of ENDS products through a heightened, retroactively applied evidentiary standard, it should have to do so in the context of a company whose evidentiary showing was so robust that FDA's own career experts recommended granting its menthol-flavored ENDS PMTAs before being overruled by new FDA political leadership. *Amicus* respectfully submits that this Court will not receive a fair picture of the deeply important issues at stake here if it reviews only FDA's action in a case like *Wages*, where the applicants sought to market such products as "Iced Pineapple Express" and "Killer Kustard Blueberry," *see* Pet.6, and which applications did not contain the same robust evidence of adult benefit and lack of youth appeal supporting *Amicus*' menthol-flavored ENDS PMTAs.

ARGUMENT

I. FDA Has Engaged In An Unlawful Scheme To Ban All Non-Tobacco-Flavored ENDS

FDA has engaged in a two-step strategy to ban non-tobacco-flavored ENDS: first, by retroactively imposing a heightened and vague evidentiary burden on already pending fruit-, candy-, and dessert-flavored ENDS PMTAs, and second, by extending that new standard to pending menthol-flavored ENDS PMTAs. FDA never suggested this new burden—namely, that ENDS applicants must provide long-term studies designed to show that their non-

tobacco-flavored ENDS have some unspecified degree of added switching benefit over tobacco-flavored ENDS—to regulated parties. FDA's approach is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" as to both steps of its unlawful scheme. 5 U.S.C. § 706(2)(A).

1. FDA commenced its effort to ban non-tobacco-flavored ENDS by first targeting fruit-, candy-, and dessert-flavored ENDS, contrary to the fair-notice principles that govern agency conduct. *See Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020).

FDA's public guidance on PMTAs, which ENDS manufacturers relied upon in preparing their applications, nowhere suggested that manufacturers should design long-term switching studies to compare the efficacy of fruit-, candy-, and dessert-flavored ENDS as against tobacco-flavored ENDS. For instance, while FDA's 2019 guidance document on ENDS PMTAs advised applicants to compare the physiological health risks of their ENDS as against other ENDS and combustibles, that guidance did not say anything about performing comparative switching studies. *See* FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems* (June 2019). And in its 2019 proposed rule on ENDS PMTAs, the agency stated that FDA did "not expect that long-term clinical studies (i.e., those lasting approximately 6 months or longer) [would]

need to be conducted for each" application. *See* 84 Fed. Reg. 50,566, 50,619 (proposed Sept. 25, 2019).

But then in July 2021, FDA circulated an internal memorandum stating that the agency would now be applying a new "standard for evidence" when assessing marketing applications for "flavored" ENDS products (a category that FDA then defined to mean fruit-, candy-, and dessert-flavored ENDS, and not menthol- and tobacco-flavored ENDS). *See* Mem. from Anne Radway, Assoc. Dir., Div. of Regul. Project Mgmt., FDA, ENDS Containing Non-Tobacco-Flavored E-Liquid 1 (July 9, 2021).[4] PMTAs with a "fatal flaw" under this new approach—specifically, a lack of long-term studies showing that the applicant's "flavored" ENDS have some undefined added benefit over tobacco-flavored ENDS in reducing or stopping combustible cigarette consumption—would "likely" be denied. *Id.* at 2. On August 17, 2021, FDA circulated another internal memorandum again stating that a "flavored" ENDS applicant must provide long-term studies showing that the applicant's product was more effective in helping current smokers reduce or quit smoking than an "appropriate comparator" tobacco-flavored ENDS product. *See* Mem. from Benjamin Apelberg, Deputy Dir., Off. of Sci., FDA, PMTA Review: Evidence to Demonstrate Benefit of

[4] Available at https://files.vaporvoice.net/wp-content/uploads/sites/3/2021/11/CTP-OS-Memos-from-Triton-Administrative-Record.pdf.

Flavored ENDS to Adult Smokers (Aug. 17, 2021).[5] FDA then purported to rescind this memorandum on August 25, 2021, shortly before denying *en masse* thousands of fruit-, candy-, and dessert-flavored ENDS applications. *See* Mem. from Benjamin Apelberg, Deputy Dir., Off. of Sci., FDA, Rescission of Aug. 17, 2021, Mem. re PMTA Review (Aug. 25, 2021);[6] Press Release, FDA, *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products* (Aug. 26, 2021).[7]

FDA has since denied every PMTA for fruit-, candy-, or dessert-flavored ENDS that it has considered under this heightened, retroactively imposed standard, without regard to its alleged rescission of the memorandum. *See* FDA, *Tobacco Products Marketing Orders* (last rev. Apr. 15, 2024).[8] "[M]onths after receiving hundreds of thousands of applications predicated on its instructions, FDA

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[5] Available at https://files.vaporvoice.net/wp-content/uploads/sites/3/2021/11/CTP-OS-Memos-from-Triton-Administrative-Record.pdf.

[6] Available at https://files.vaporvoice.net/wp-content/uploads/sites/3/2021/11/CTP-OS-Memos-from-Triton-Administrative-Record.pdf.

[7] Available at https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence.

[8] Available at https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders.

turned around, pretended it never gave anyone any instructions about anything, imposed new testing requirements without any notice, and denied all one-million flavored e-cigarette applications for failing to predict the agency's volte face." *Wages & White Lion Invs., LLC v. FDA*, 90 F.4th 357, 362 (5th Cir. 2024).

2. The agency's bait-and-switch was even more egregious and legally indefensible with respect to menthol-flavored ENDS.

Prior to issuing its MDO for *Amicus*' menthol-flavored ENDS—which was the first MDO issued based on what FDA asserted to be a "full scientific review" for any menthol-flavored ENDS, *see* Press Release, FDA, *FDA Denies Marketing of Logic's Menthol E-Cigarette Products* (Oct. 26, 2022)[9]—FDA explained to menthol-flavored ENDS manufacturers that (i) the agency understood menthol-flavored ENDS to have an added benefit over other flavored ENDS, given that these products could help current menthol smokers reduce or stop smoking combustibles, and (ii) the agency would not require any evidence comparing the switching efficacy of menthol- versus tobacco-flavored ENDS. In 2020, FDA issued a guidance document detailing its enforcement priorities with respect to ENDS

[9] Available at https://web.archive.org/web/20230126131134/https:/www.fda.gov/news-events/press-announcements/fda-denies-marketing-logics-menthol-e-cigarette-products-following-determination-they-do-not-meet.

products, which explicitly distinguished between "flavored" ENDS products—that is, fruit-, candy-, and other dessert-flavored ENDS—on the one hand, and tobacco- and menthol-flavored ENDS products, on the other. *See* FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* (Apr. 2020).[10] FDA explained that it would prioritize enforcement against "flavored, cartridge-based ENDS products (other than tobacco- and menthol-flavored)." *See id.* at 20. "This approach strikes an appropriate balance between restricting youth access to [fruit and other candy-like flavored products], while maintaining availability of potentially less harmful options for current and former adult smokers who have transitioned or wish to transition completely away from combusted tobacco products." *Id.*

Reinforcing this message, after *Amicus* and other ENDS manufacturers had already submitted PMTAs for ENDS products in fruit, tobacco, and menthol flavors, the agency sent *Amicus* and other manufacturers deficiency letters outlining additional information that the agency now required to authorize their ENDS products, and further showing FDA's prior policy of treating the menthol flavor as distinct from fruit, candy, or dessert flavors. *See Logic Tech. Dev. LLC v. FDA*, 84 F.4th 537, 558 (3d Cir. 2023) (Porter, J., dissenting); *R.J. Reynolds*

[10] Available at https://www.fda.gov/media/133880/download.

Vapor Co. v. FDA, 65 F.4th 182, 188 (5th Cir. 2023). With respect to fruit-flavored ENDS, FDA asked *Amicus* to provide a new category of evidence: "scientific evidence and rationale to demonstrate whether these flavor variants may facilitate adult smokers switching to [*Amicus*'] products *at a rate beyond that of tobacco- or menthol-flavored products, which may have lower youth appeal*." Joint App., Vol. VII at 3016, *Logic Tech. Dev. LLC v. FDA*, No.22-3030, Doc.45 (3d Cir. Jan. 5, 2023) (emphasis added); *see R.J. Reynolds*, 65 F.4th at 188. FDA stated that this evidence could include "[d]ata or information from studies demonstrating uptake/switching among adult smokers using flavored variants of the products *relative to uptake/switching among tobacco- or menthol-flavored users*," and "[d]ata or information from studies demonstrating appeal (e.g., preference or intention to use) of flavored variants (fruit and fruit-combination flavored products) *compared to tobacco- or menthol-flavored variants* among adult users interested in switching to ENDS." Joint App., Vol. VII at 3016, *Logic*, No.22-3030, Doc.45 (3d Cir. Jan. 5, 2023) (emphases added). In *Amicus*' case, even though this deficiency letter (i) also dealt with *Amicus*' menthol-flavored ENDS PMTAs, *see id.* at 3020, and (ii) specifically requested comparative efficacy evidence for its fruit-flavored ENDS, *see id.* at 3016, the letter nowhere suggested that *Amicus* should submit data showing comparative switching efficacy as between its menthol- and tobacco-flavored ENDS.

As would later be revealed in two extraordinary internal memoranda that FDA prepared in connection with *Amicus*' menthol-flavored ENDS applications, the FDA's Center for Tobacco Products' Office of Science—applying the Tobacco Control Act's risk-benefit analysis, *see* 21 U.S.C. § 387j(c)(4), and recognizing that the menthol flavor offers unique benefits for current menthol smokers, whereas fruit-, candy-, and dessert-flavored ENDS have no lawful analogue in combustible cigarettes—unanimously recommended granting *Amicus*' PMTAs for its menthol-flavored ENDS. Joint App., Vol. III at 908, *Logic*, No.22-3030, Doc.41 (3d Cir. Jan. 5, 2023). The non-partisan, expert staff determined that, "as long as menthol-flavored cigarettes remain on the market, menthol-flavored ENDS could be a direct substitute for them, providing a less harmful alternative for menthol-flavored cigarette smokers, who are less likely to successfully quit smoking than smokers of non-menthol-flavored cigarettes." *Id.* Menthol smokers' "documented preference" for menthol, plus *Amicus*' "product-specific evidence," outweighed any risk to youth of the menthol products and so met the "legal standard for authorization." *Id.*

But then in July 2022, the Center's new political leadership overruled the Office of Science's evidence-based conclusions, and imposed FDA's unlawful, heightened evidentiary standard for fruit-, candy-, and dessert-flavored ENDS upon menthol-flavored ENDS. *Id.* at 904; *id.* at 909; *see id.* at 907–08. FDA now asserted, *based upon no new evidence*

whatsoever, that, "in light of the substantial risk to youth and the lack of robust evidence of actual differential use to quit or significantly reduce cigarettes per day, the approach to menthol-flavored ENDS should be the same as for other flavored ENDS." *Id.* at 909. In other words, FDA would deny every menthol-flavored ENDS application unless the applicant provided "robust, product-specific evidence showing that their menthol-flavored products facilitate complete switching or significant reduction in smoking . . . among adults greater than that facilitated by tobacco-flavored ENDS." *Id.* While new leadership noted that it considered the concern that its new approach to menthol-flavored ENDS would eliminate all non-tobacco-flavored ENDS products, it failed to offer any answer for this concern. *Id.* at 904 & n.3. In internal meetings, the Office of Science's staff pushed back against the agency's conduct, including for its lack of "transparency." *Id.* at 905.

Shortly thereafter, FDA issued the MDO for *Amicus*' menthol-flavored ENDS. Consistent with the new approach to menthol-flavored ENDS outlined in FDA's then-secret memoranda, the agency said that it was unable to ascertain from *Amicus*' studies or from the peer-reviewed literature "whether or to what extent [*Amicus*'] menthol-flavored products facilitate complete switching [of cigarette smokers to *Amicus*' products] or significant cigarette reduction as compared to tobacco-flavored ENDS products." Pet. for Writ of Cert. at 64a, *Logic*, No.23-1125. The nature of FDA's reasoning and the evidence before the

agency demonstrated that FDA designed its new anti-menthol ENDS policy to be so malleable as to allow FDA to deny all menthol-flavored ENDS. It so happens that *Amicus*' data *did* show that its menthol-flavored ENDS have a comparative benefit over tobacco-flavored ENDS in terms of switching because *Amicus* happened to submit its tobacco-flavored and menthol-flavored ENDS PMTAs at the same time. *See* Suppl. App. at 87, *Logic*, No.22-3030, Doc.65 (3d Cir. Feb. 1, 2023). In particular, *Amicus*' data showed that 76% of study participants who received the Logic Power menthol flavor reduced their cigarettes per day by 80% or more by the end of a 60-day study, whereas 63% of participants who received the Logic Power tobacco flavor reduced their cigarettes per day by 80% or more by the end of that study. *Id.* FDA did not address this data or explain why it did not satisfy the agency's new comparative-efficacy standard as to menthol-flavored ENDS. *See, e.g.*, Pet. for Writ of Cert. at 204a–205a, *Logic*, No.23-1125. Rather, FDA simply declared that *Amicus*' evidence was not "acceptably strong" enough to demonstrate "an added benefit relative to that of tobacco-flavored ENDS in facilitating adult smokers completely switching away from or significantly reducing their smoking." *Id.*

FDA then relied upon its new standard to issue MDOs for every menthol-flavored ENDS application it has considered. *See* FDA, *Tobacco Products Marketing Orders*, *supra*. As with fruit-, candy-, and dessert-flavored ENDS, the agency has denied these menthol applications for purportedly failing to

provide long-term studies designed to show, to some unspecified degree, that menthol-flavored ENDS have an added benefit over tobacco-flavored ENDS in helping adults reduce or quit smoking. *See R.J. Reynolds*, 65 F.4th at 188; Pet'r's Br. at 17–18, *SWT Glob. Supply, Inc. v. FDA*, No.23-2403 (8th Cir. filed Sept. 14, 2023); *see also* FDA, *FDA Denies Marketing Applications for Flavored blu E-Cigarette Products* (Feb. 5, 2024);[11] FDA, *FDA Denies Marketing of myblu Menthol E-Cigarette Product* (July 10, 2023).[12]

II. If This Court Grants The Present Petition, It Should Also Grant *Amicus*' Petition And Decide Both Petitions Together

If this Court grants the instant Petition to decide whether FDA's approach to fruit-, candy-, and dessert-flavored ENDS PMTAs was unlawful, *Amicus* respectfully submits that this Court should also grant its pending petition, *see* Pet. for Writ of Cert., *Logic*, No.23-1125, which presents the related but importantly distinct question of whether FDA acted unlawfully by retroactively extending its heightened evidentiary standard for fruit-, candy-, and dessert-flavored ENDS to menthol-flavored ENDS.

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[11] Available at https://www.fda.gov/tobacco-products/ctp-newsroom/fda-denies-marketing-applications-flavored-blu-e-cigarette-products.

[12] Available at https://www.fda.gov/tobacco-products/ctp-newsroom/fda-denies-marketing-myblu-menthol-e-cigarette-product.

Reviewing these two petitions together is important for at least three reasons.

First, there is a related, but clearly distinct, circuit split on this second Question Presented. While the Third Circuit's divided decision below held that FDA did not unlawfully apply a new and heightened evidentiary standard retroactively to menthol-flavored ENDS PMTAs, *see Logic*, 84 F.4th 537, 553–555, the Fifth Circuit has reached the opposite conclusion, *see R.J. Reynolds*, 65 F.4th 189–94. In staying an MDO for R.J. Reynolds' menthol-flavored ENDS PMTAs, the Fifth Circuit held that FDA violated the principles of fair notice without adequate justification in evaluating menthol-flavored ENDS applications. 65 F.4th at 189–91, 195. While this decision arose in the stay posture, the Fifth Circuit has since relied upon *R.J. Reynolds* repeatedly as circuit precedent in administrative law cases. *See, e.g.*, *Inhance Techs., LLC v. EPA*, 96 F.4th 888, 895 (5th Cir. 2024); *Chamber of Comm. of U.S. v. SEC*, 85 F.4th 760, 777 n.23 (5th Cir. 2023).

Second, FDA's effort to impose retroactively a heightened evidentiary standard for already-pending PMTAs is most practically important and legally indefensible in the context of menthol-flavored ENDS. As FDA leadership previously explained, menthol-flavored ENDS "may be important to adult smokers seeking to transition away from cigarettes" given that "combustible cigarettes are still sold in menthol flavor." Statement of Commissioner

Gottlieb, *supra*. Menthol-flavored cigarettes make up roughly 37% of cigarette sales in the United States. *See Menthol Tobacco Products*, *supra*. FDA's own career experts, in turn, recognized that menthol-flavored ENDS are helpful to adults seeking to transition away from combustibles when they recommended granting *Amicus*' PMTAs. *See* Joint App., Vol. III at 908, *Logic*, No.22-3030, Doc.41 (3d Cir. Jan. 5, 2023). Further, the evidence before FDA shows that the menthol flavor is less popular among youth than candy, fruit, and dessert flavors, *see* Joint App., Vol. III at 1158–59, *Logic*, No.22-3030, Doc.41 (3d Cir. Jan. 5, 2023), meaning that it is nonsensical to apply the "same," *id.* at 909, burden as to adult benefit to menthol-flavored ENDS as FDA has decided to apply to candy, fruit, and dessert flavors.

Finally, if FDA is going to come before this Court to defend its blanket anti-ENDS policy, it should have to justify its conduct where it is least defensible and most harmful to the public. *See* Pet.6–7. As the Solicitor General notes in the instant Petition, the *Wages* applicants did not design "well-controlled investigations," 21 U.S.C. § 387j(c)(5)(A), "to determine whether e-cigarette flavors aid in smoking cessation," Pet.16 (citation omitted), while seeking to market products such as "Iced Pineapple Express," "Killer Kustard Blueberry," and "Suicide Bunny Mother's Milk and Cookies," *see* Pet.6. In contrast, *Amicus* submitted powerful evidence that its menthol-flavored ENDS are beneficial for adult smokers and are not used by youth in any appreciable

amounts. For example, *Amicus*' 60-day studies showed that 76% of study participants who received the Logic Power menthol flavor reduced their cigarettes per day by 80% by the end of the study. Suppl. App. at 87, *Logic*, No.22-3030, Doc.65 (3d Cir. Feb. 1, 2023). Further, data that FDA relied upon did not identify *any* youth who reported Logic as their regular brand. Joint App., Vol. III at 1159, *Logic*, No.22-3030, Doc.41 (3d Cir. Jan 5, 2023). FDA should have to defend its campaign against non-tobacco-flavored ENDS in the context of *Amicus*' PMTAs, where the menthol flavor is unquestionably more important to the goal of reducing use of combustible cigarettes, and the evidence of adult benefit and lack of youth appeal was so robust that the Office of Science recommended granting authorization before the agency's new leadership retroactively imposed a heightened evidentiary burden on menthol-flavored ENDS.

CONCLUSION

If this Court grants certiorari to review the instant Petition, *Amicus* respectfully requests that it also grant certiorari to review *Amicus*' pending petition.

Respectfully submitted,

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