No. 23-1125

In the Supreme Court of the United States

LOGIC TECHNOLOGY DEVELOPMENT LLC,
PETITIONER,
v.
FOOD AND DRUG ADMINISTRATION

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

SUPPLEMENTAL BRIEF FOR PETITIONER

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SUPPLEMENTAL BRIEF

In *Food & Drug Administration v. Wages & White Lion Investments, LLC*, 604 U.S. ___, 2025 WL 978101 (2025), this Court addressed whether the Food and Drug Administration ("FDA") violated the Administrative Procedure Act ("APA") when issuing marketing denial orders for fruit-, candy-, and dessert-flavored Electronic Nicotine Delivery Systems ("ENDS"). *Wages* applied the APA's "change-in-position doctrine," which "ask[s] whether the FDA changed course and, if it did, whether it offered satisfactory reasons for the change." 2025 WL 978101, at *13. *Wages* held that FDA did not violate this doctrine in adopting a "comparative-efficacy standard" requiring fruit-, candy-, and dessert-flavored ENDS companies to compare their products' switching benefits to those of tobacco-flavored ENDS. In reaching this conclusion, *Wages* explained that FDA's prior industry guidance "emphasized the importance of cross-product comparators and the FDA's specific worry that dessert-, candy-, and fruit-flavored products would appeal to youth more than *tobacco- and menthol-flavored products*." *Id.* at *20 (emphasis added). FDA's position on the appropriate comparators for fruit-, candy-, and dessert-flavored ENDS was a "natural consequence of [this] predecisional guidance." *Id.* at *19.

Petitioner Logic Technology Development LLC's ("Logic") pending Petition For A Writ Of Certiorari raises two Questions Presented.

In its first Question Presented, Logic asks this Court to decide whether FDA's adoption of its comparative-efficacy standard for fruit-, candy-, and dessert-flavored ENDS violated the APA, including the change-in-position doctrine. Pet.27–30. As Logic explained, this is the same Question Presented that was before this Court in *Wages*, Pet.27, and *Wages* now has answered this Question in FDA's favor.

In its second Question Presented, Logic asks this Court to decide whether FDA violated the APA's change-in-position doctrine and acted arbitrarily and capriciously as a substantive matter by retroactively imposing the same comparative-efficacy standard upon applications for menthol-flavored ENDS. As Logic explained, independent of whether FDA violated the APA with regard to fruit, candy, and dessert flavors, the agency's conduct with respect to *menthol* was unlawful. Pet.31–42. FDA's predecisional guidance consistently treated menthol and tobacco flavors together, thus clearly informing Logic and other menthol-flavored ENDS companies that there was no reason to design studies comparing the efficacy of menthol- versus tobacco-flavored

products. Pet.32. FDA also conveyed that position in letters to menthol-flavored ENDS companies, telling them to submit comparative-efficacy evidence vis-à-vis the tobacco flavor for fruit-, candy-, and dessert-flavored ENDS, while making no mention of such evidence for menthol-flavored ENDS. Pet.32–34.

This was FDA's position for years before it decided to reverse course retroactively, as confirmed in FDA's extraordinary internal memoranda. These memoranda reveal that FDA's career experts, after reviewing Logic's extensive data, unanimously recommended granting Logic's applications for its menthol-flavored ENDS prior to changing course. *See* Pet.19. Simply put, even FDA's own career experts did not think the tobacco-flavor comparative-efficacy standard applied to menthol-flavored ENDS applications when Logic submitted its application.

As Judge Porter explained in his dissent below, whether FDA violated the APA as to menthol-flavored ENDS is distinct from whether FDA violated the APA with respect to fruit-, candy-, and dessert-flavored ENDS. Pet.App.56a n.3 (Porter, J., dissenting). *Wages* does not answer this second Question Presented and it remains subject to a circuit split, *see R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 189–91, 195 (5th Cir. 2023), which split is important to the

multibillion-dollar menthol-flavored ENDS industry and those trying to reduce or quit smoking menthol combustible cigarettes, *see* Pet.42–45.

In light of the Court's holding and reasoning in *Wages*, Logic respectfully submits that this Court should grant Logic's Petition on the second Question Presented on the merits or, at a minimum, grant, vacate, and remand for the Third Circuit to reconsider the decision below in light of *Wages*.

A. This Court should grant the Petition and resolve Logic's second Question Presented, for all of the reasons that Logic articulated in its Petition.

Wages held that FDA's decision to create and apply a comparative-efficacy standard for fruit-, candy-, and dessert-flavored ENDS applications—requiring those applications to show that these products have an added benefit over tobacco-flavored ENDS in helping adult smokers reduce or quit smoking—did not violate the APA. *See* 2025 WL 978101, at *18–20. This Court did not decide whether FDA's retroactive extension of that same standard to pending applications for menthol-flavored ENDS was lawful. As more fully set forth below, this is a very different question, as FDA itself previously went to great lengths to differentiate between fruit, candy,

and dessert flavors, on the one hand, and menthol and tobacco flavors, on the other hand. Logic's second Question Presented asks this question, which remains subject to a circuit split between the Third and Fifth Circuits. *Compare Logic Tech. Dev. LLC v. FDA*, 84 F.4th 537, 553–55 (3d Cir. 2023), *with R.J. Reynolds*, 65 F.4th at 189–91, 195.

Logic's second Question Presented also asks this Court to decide whether FDA's conduct with respect to menthol-flavored ENDS was substantively unlawful, an issue that *Wages* did not address. As Logic's Petition explains, it was arbitrary and capricious for FDA to apply the same comparative-efficacy standard to menthol-flavored ENDS that FDA applied to fruit-, candy-, and dessert-flavored ENDS, where it is undisputed that menthol-flavored ENDS continue to be significantly less popular among youth than other flavored ENDS, and menthol cigarettes are lawfully sold and popular. Pet.37–38, 40. Relatedly, whether FDA can deny menthol-flavored ENDS applications in the manner in dispute in this case is critically important, given that menthol-flavored ENDS offer a valuable resource for current adult menthol smokers looking to reduce or quit smoking combustible cigarettes.

B. Alternatively, this Court should grant the Petition, vacate the decision below, and remand with instructions for the Third Circuit to apply the change-in-position doctrine as set forth in *Wages*.

1. As *Wages* explains, the change-in-position analysis proceeds in two steps. First, the court must decide "whether an agency changed existing policy," that is, whether the agency has "act[ed] 'inconsistent[ly]' with an 'earlier position'" or "perform[ed] 'a reversal of [its] former views as to the proper course.'" 2025 WL 978101, at *14 (second and fourth alterations in original) (first quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 224 (2016); and then *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983)). Second, "[o]nce a change in agency position is identified," the court must decide whether the agency "display[ed] awareness that it is changing position," "offer[ed] 'good reasons for the new policy,'" and was "cognizant that [its] longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Id.* (first quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); and then *Encino Motorcars*, 579 U.S. at 221–22).

FDA's treatment of *menthol*-flavored ENDS violates this test under *Wages*' reasoning.

On the first step, FDA plainly "revers[ed]" its "former views" on the menthol flavor in denying marketing authorization for Logic's menthol-flavored products. *Id.* (citations omitted). Before that denial, FDA's industry guidance specifically and consistently grouped menthol- and tobacco-flavored ENDS together. Pet.32. As *Wages* explains, FDA's guidance "emphasized the importance of cross-product comparators and the FDA's specific worry that dessert-, candy-, and fruit-flavored products would appeal to youth *more than tobacco- and menthol-flavored products*." 2025 WL 978101, at *20 (emphasis added); Pet.12 (discussing FDA's 2020 guidance acknowledging the agency's distinction between flavored ENDS, on the one hand, and tobacco- and menthol-flavored ENDS, on the other hand (citing JA.1126)); Pet.32 ("[m]enthol is unique compared to other available ENDS product flavors as it is the only characterizing flavor available in cigarettes, and it may reduce the irritation and harshness of smoking" (quoting JA.1129)). Given FDA's consistent grouping of the menthol and tobacco flavors as equivalent, Logic and other applicants had no reason to develop or highlight evidence showing that their menthol-flavored ENDS are more effective

than tobacco-flavored ENDS in helping adult smokers reduce or quit smoking. Pet.32–33.

FDA further conveyed its position that the menthol and tobacco flavors are substantially equivalent, meaning that applicants would have no need to compare the efficacy of menthol- and tobacco-flavored products, in its deficiency letters. In a 2020 deficiency letter to Logic addressing all of Logic's applications (for fruit, menthol, and tobacco flavors), FDA specifically asked for evidence comparing the efficacy of fruit- versus tobacco- and menthol-flavored products, but did not request any comparison as between menthol- and tobacco-flavored products. Pet.13. The 2020 deficiency letter is materially identical to the deficiency letter that the Fifth Circuit addressed in *R.J. Reynolds*, which similarly instructed the company to "provide evidence to demonstrate that the use of these flavored products (*other than menthol*) increases the likelihood of complete switching among adult smokers relative to tobacco or menthol-flavored products." 65 F.4th at 188. The only plausible inference that Logic and other menthol-flavored ENDS companies could have drawn from these deficiency letters is that FDA did not believe the same comparison with tobacco-flavored ENDS was necessary for menthol-flavored ENDS. *See* Pet.App.57a. That is especially so when

viewed in conjunction with FDA's public guidance repeatedly explaining the agency's "heightened concern with dessert-, candy-, and fruit-flavored products compared to tobacco- and menthol-flavored products," which guidance *Wages* highlights. 2025 WL 978101, at *19.

FDA's extraordinary internal memoranda make clear that FDA's own career experts understood FDA's position with respect to menthol the same way that Logic and all other menthol-flavored ENDS companies did, prior to the agency's course reversal. As Logic has explained in its Petition, the internal memoranda reveal that FDA's Center for Tobacco Products' Office of Science unanimously recommended granting marketing authorization for Logic's menthol-flavored ENDS, concluding that Logic's applications complied with the Tobacco Control Act and all extant agency guidance without any mention of Logic's alleged failure to compare the efficacy of its menthol products to that of tobacco products. Pet.19. The memoranda reveal beyond any dispute that it was not until well after Logic and many other applicants had submitted their applications that FDA decided to impose, retroactively, a new policy "lump[ing] menthol together with fruit, candy, and dessert flavors." Pet.App.41a (Porter, J., dissenting). Indeed, even

FDA does not dispute that the internal memoranda show a previously undisclosed change in FDA's policy on menthol-flavored ENDS. *See* FDA Br.12–13. This satisfies step one of this Court's change-in-position doctrine. *See Wages*, 2025 WL 978101, at *13 (citing *Encino Motorcars*, 579 U.S. at 221–22).

With respect to step two of the change-in-position analysis, not only did FDA fail to provide "good reasons" for its changed position on menthol, it also completely ignored Logic's and other menthol-flavored ENDS companies' "serious reliance interests." *Id.* at *14 (citations omitted). Nowhere in FDA's marketing denial order does the agency take into account Logic's substantial reliance interests, where Logic spent millions designing studies and preparing applications based on FDA's prior policy only to have FDA reverse course.

2. The Third Circuit panel majority below did not conduct the change-in-position analysis in the manner that *Wages* requires. As to the first prong of that analysis, while the Third Circuit recognized that FDA had foreshadowed "the need for robust cross-product comparisons (including on the dimension of flavor)," it ignored the fact that "FDA's comparative-efficacy standard was a natural consequence" of its "heightened concern with dessert-, candy-, and fruit-

flavored products compared to tobacco- and menthol-flavored products." *Id.* at *19. The Third Circuit did not address FDA's many statements making clear the agency's prior position that the tobacco and menthol flavors are comparable in terms of youth appeal, such that the tobacco flavor is not a comparator for purposes of obtaining marketing authorization for a menthol-flavored ENDS product. *E.g.*, *id.* (noting FDA's public guidance that it would "'prioritize enforcement of flavored' e-cigarette products 'other than tobacco- and menthol-flavored products'" (citation omitted)). Nor did the Third Circuit conduct the second step of *Wages*' change-in-position analysis. The Third Circuit did not make any inquiry at all into whether FDA offered "good reasons for [its] new policy," nor did it "take[ ] into account" Logic's "serious reliance interests." *Id.* at *14 (citation omitted). Again, those reliance interests are particularly significant here, where Logic invested tens of millions of dollars to prepare marketing applications for menthol-flavored ENDS products that FDA's own career experts initially recommended approving prior to reversing course under new leadership. Pet.10, 19–20.

CONCLUSION

This Court should grant certiorari and review Logic's second Question Presented on the merits or, in the alternative, grant, vacate, and remand for the Third Circuit to apply this Court's *Wages* decision.

Respectfully submitted,

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