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

Petitioner Logic Technology Development LLC ("Logic") submits this supplemental brief in response to the Solicitor General's June 24, 2024, letter regarding the Food and Drug Administration's ("FDA") recent grant of marketing authorization to certain of NJOY LLC's ("NJOY") menthol-flavored e-cigarette ("ENDS") products. *See* FDA, Technical Project Lead (TPL) Review of PMTAs (June 2024) (hereinafter, "NJOY TPL").*

In the NJOY marketing granted order, FDA applied the same heightened evidentiary standard as it did to Logic's premarket tobacco product applications ("PMTAs"), requiring NJOY to show that its menthol-flavored ENDS help adult smokers switch from smoking cigarettes to some unspecified† higher

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* Available at https://www.fda.gov/media/179501/download?attachment (last visited June 25, 2024).

† FDA concluded that NJOY satisfied this standard by submitting studies demonstrating that NJOY's DAILY menthol-flavored ENDS showed switching rates of 32-43% versus tobacco-flavored ENDS at 21-37%. *See* NJOY TPL, *supra*, at 8. In contrast, FDA never engaged with Logic's evidence showing that 76% of study participants who received the Logic Power

degree than do tobacco-flavored ENDS. *See id.* at 44–45. Notably, NJOY amended its PMTAs in December 2022, two months after FDA issued its decision denying marketing authorization to Logic's menthol-flavored ENDS in October 2022, to try to meet FDA's new comparative-efficacy standard. *See id.* at 42.

The NJOY marketing granted order supports this Court granting review on Logic's Petition (rather than, as FDA has argued, holding this Petition for FDA's petition in *FDA v. Wages & White Lion Investments, LLC*, No.23-1038 (filed Mar. 19, 2024)), for three reasons.

First, Logic's second Question Presented asks this Court to resolve the circuit split over whether FDA can lawfully impose its heightened evidentiary standard—which FDA first developed for fruit-, candy-, and dessert-flavored ENDS—on menthol-flavored ENDS. Pet.33–35; *see Logic Tech. Dev. LLC v. FDA*, 84 F.4th 537, 553 (3d Cir. 2023) ("part[ing] ways with the Fifth Circuit['s]" decision in *R.J.*

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menthol flavor reduced their cigarettes per day by 80% or more by the end of 60 days, whereas 63% of participants who received the Logic Power tobacco flavor reduced their cigarettes per day by 80% or more by the end of 60 days. Pet.21–22.

Reynolds Vapor Co. v. FDA, 65 F.4th 182 (5th Cir. 2023), on this Question Presented). That FDA continues to impose this heightened standard on menthol-flavored ENDS PMTAs demonstrates the ongoing significance of this circuit split to the multibillion-dollar menthol-flavored ENDS industry.

Second, that NJOY had to amend its pending PMTAs to address FDA's new heightened evidentiary standard underscores the importance of this Court addressing this issue now, rather than after this Court decides *Wages*. After all, menthol-flavored ENDS companies need to know whether they must follow NJOY's lead by trying to meet FDA's new standard, including potentially spending millions of dollars on studies addressing a standard that the Fifth Circuit held FDA had no authority to impose, but which the Third Circuit has blessed.

Third, that NJOY amended its PMTAs in December 2022 to meet the new heightened standard, after FDA announced that the standard would apply to menthol-flavored ENDS in denying Logic's PMTAs in October 2022, strongly supports the Fifth Circuit's holding in *R.J. Reynolds* (and Logic's argument in its Petition, Pet.35–39) that FDA denying PMTAs through retroactive imposition of its unlawful, heightened standard on already-submitted

applications violated the Administrative Procedure Act ("APA") by "penalizing" companies like Logic (and R.J. Reynolds) "for 'good-faith reliance' on the agency's prior positions." *R.J. Reynolds*, 65 F.4th at 189 (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156–57 (2012)).

CONCLUSION

This Court should grant the Petition.

Respectfully submitted,

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