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

BRIEF FOR THE RESPONDENT

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QUESTIONS PRESENTED

The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Div. A, 123 Stat. 1776, requires a person to obtain authorization from the Food and Drug Administration (FDA) before introducing a new tobacco product into interstate commerce. The agency may grant such authorization only if the applicant shows, among other things, that the marketing of the product would be "appropriate for the protection of the public health." 21 U.S.C. 387j(c)(2)(A). In this case, the agency denied petitioner's applications for authorization to market new menthol-flavored e-cigarette products because petitioner had failed to show that marketing the products would be appropriate for the protection of the public health. The questions presented are:

1. Whether FDA acted arbitrarily and capriciously in evaluating applications for authorization to market flavored e-cigarette products in general.

2. Whether FDA acted arbitrarily and capriciously in denying petitioner's applications for authorization to market menthol-flavored e-cigarette products in particular.

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-59a) is reported at 84 F.4th 537.

JURISDICTION

The judgment of the court of appeals was entered on October 19, 2023. A petition for rehearing was denied on December 15, 2023 (Pet. App. 228a-229a). On February 26, 2024, Justice Alito extended the time within which to file a petition for a writ of certiorari to and including April 15, 2024, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Family Smoking Prevention and Tobacco Control Act (Act), Pub. L. No. 111-31, Div. A, 123 Stat. 1776, requires a manufacturer to obtain authorization

from the Food and Drug Administration (FDA) before introducing any "new tobacco product" into interstate commerce. 21 U.S.C. 387j(a)(2)(A). The Act defines a new tobacco product as a tobacco product that was not on the market as of February 15, 2007. See 21 U.S.C. 387j(a)(1).

FDA may grant marketing authorization only if the manufacturer shows, among other things, that the product would be "appropriate for the protection of the public health." 21 U.S.C. 387j(c)(2)(A). In applying that standard, FDA must consider both the "likelihood that existing users of tobacco products will stop using such products" and the "likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. 387j(c)(4). In the present context, that standard requires the agency to weigh (1) the likelihood that the new product will help existing smokers (generally adults) completely switch to less dangerous alternatives, or significantly reduce the amount they smoke, against (2) the risk that the new product will entice new users (generally youth) to begin using tobacco products.

This case concerns FDA's application of those provisions to e-cigarettes—that is, devices that aerosolize nicotine-laced "e-liquids" that users then inhale. See Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Services, *E-Cigarette, or Vaping, Products Visual Dictionary* 7. In 2016, FDA promulgated a rule announcing that it would regulate e-cigarettes and e-liquids in accordance with the Act. See *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for To-*

bacco Products, 81 Fed. Reg. 28,974, 29,028-29,044 (May 10, 2016). E-cigarettes and e-liquids generally qualify as "new tobacco products" because they were not on the market as of February 15, 2007. See *Avail Vapor, LLC* v. *FDA*, 55 F.4th 409, 414 (4th Cir. 2022), cert. denied, 144 S. Ct. 277 (2023).

2. In 2019, petitioner applied for authorization to market e-cigarette devices and e-cigarette products in various flavors (tobacco, fruit, and menthol). See Pet. App. 11a; C.A. App. 1299, 1316, 1333. In March 2022, FDA granted authorization to market the devices and tobacco-flavored products; denied authorization to market the fruit-flavored products; and deferred a decision on the menthol-flavored products in order to allow more time to judge whether any factors unique to menthol affected the public-health assessment. See Press Release, FDA, *FDA Issues Decisions on Additional E-Cigarette Products* (Mar. 24, 2022); C.A. App. 943. Then, in October 2022, FDA denied authorization to market the menthol-flavored products. See Pet. App. 19a. "[O]nly the FDA's rejection of [the] menthol-flavored [products] is at issue" here. *Id.* at 11a n.8.

FDA found insufficient evidence that the benefits of petitioner's menthol-flavored products outweighed the products' risks. See C.A. App. 1. First, FDA found substantial evidence that menthol flavoring "has significant appeal to youth," *id.* at 2, and explained that young people's rate of using menthol-flavored e-cigarettes was similar to their rate of using products with other flavorings, such as mint and candy, see *id.* at 947. FDA also cited a study showing that petitioner's brand was one of the ten most popular e-cigarette brands for middle- and high-school students in the United States. See *id.* at 1159.

Second, FDA found insufficient evidence that petitioner's menthol-flavored products would provide a benefit to adult smokers, relative to tobacco-flavored products, that would outweigh the risk to youth. See C.A. App. 2. FDA evaluated petitioner's evidence, including evidence from randomized controlled trials, but explained that the results of those studies did not show that petitioner's "menthol-flavored new products are more likely to promote complete switching or significant cigarette reduction compared to tobacco-flavored products." *Ibid.*; see *id.* at 916, 966. FDA added that the published literature "does not demonstrate that menthol-flavored [e-cigarettes] are more effective in promoting complete switching or significant cigarette reduction relative to tobacco-flavored [e-cigarettes]." *Id.* at 2. FDA accordingly denied the applications. See *id.* at 1.

3. Petitioner filed a petition for review in the Third Circuit. See Pet. App. 19a. The court initially granted petitioner's motion to stay the denial order pending the disposition of the petition for review. See *ibid.* After briefing and argument, however, the court denied the petition. See *id.* at 1a-59a.

As relevant here, the court of appeals rejected petitioner's contention that FDA had unfairly surprised applicants by changing the evidentiary standards under which it would evaluate applications to market menthol-flavored e-cigarettes. See Pet. App. 29a-33a. The court explained that FDA had evaluated menthol-flavored e-cigarettes under "the same regulatory framework and evidentiary standard that the agency had applied previously to other non-tobacco flavored" products. *Id.* at 29a-30a.

The court of appeals also rejected petitioner's contention that FDA's political leadership improperly "overrode" the expert judgments of career officials and imposed a secret "blanket anti-menthol policy." Pet. App. 23a; see *id.* at 23a-29a. The court explained that the internal documents cited by petitioner showed only that the Office of Science, a component of FDA's Center for Tobacco Products, was "preliminarily inclined to recommend approval" of petitioner's applications, but later reassessed its view after discussions with the Center's Director, and determined that it was "reasonable and consistent to treat menthol-flavored [products] in the same way as other non-tobacco-flavored [products]." *Id.* at 24a.

Finally, the court of appeals rejected the contention that FDA had improperly discounted petitioner's "'product-specific' evidence," including a plan that would purportedly have mitigated the products' risks to children by restricting their marketing. Pet. App. 34a (citation omitted); see *id.* at 34a-38a. The court explained that FDA had not "ignored the evidence"; rather, it simply "did not weigh the evidence to [petitioner's] liking." *Id.* at 35a. In particular, "FDA did analyze [petitioner's] marketing plan and found it lacking." *Id.* at 38a.

Judge Porter dissented. See Pet. App. 41a-59a. In his view, FDA had arbitrarily and capriciously "lumped menthol together with fruit, candy, and dessert flavors" without providing an adequate justification for doing so. *Id.* at 41a.

4. The court of appeals denied petitioner's petition for rehearing en banc. See Pet. App. 228a-229a. But the court granted petitioner's motion for a stay of its

mandate pending disposition of the petition for a writ of certiorari. See C.A. Doc. 126.

DISCUSSION

The petition for a writ of certiorari in this case presents two questions. The first question—whether FDA has acted arbitrarily and capriciously in evaluating applications to market flavored e-cigarette products in general—overlaps with the question presented in the government's petition for a writ of certiorari in *FDA* v. *Wages & White Lion Investments, L.L.C.*, No. 23-1038 (filed Mar. 19, 2024). As explained below, *Wages & White Lion* is a better vehicle than this case for resolving that question. The second question—whether FDA has acted arbitrarily and capriciously in evaluating applications to market menthol-flavored e-cigarette products in particular—does not warrant this Court's review at this time. The court of appeals' resolution of that question was correct, and its decision does not conflict with any decision of this Court or any merits decision of any other court of appeals. The Court should therefore grant the petition in *Wages & White Lion* and hold the petition in this case pending the resolution of *Wages & White Lion*.

A. *Wages & White Lion* Is A Better Vehicle Than This Case For Resolving The First Question Presented

The first question presented is "[w]hether [FDA's] creation of a new, heightened standard for evaluating already-pending premarket tobacco product applications * * * for certain electronic nicotine delivery systems * * * was [arbitrary and capricious]." Pet. i. That question concerns flavored e-cigarettes generally. The second question presented concerns menthol-flavored e-cigarettes in particular. See *ibid.*

As petitioner acknowledges (Pet. 3, 29-30), the government's pending petition for a writ of certiorari in *Wages & White Lion* likewise presents the first question presented here: whether FDA has acted arbitrarily and capriciously in denying applications for authorization to market flavored e-cigarette products. For several reasons, *Wages & White Lion* is a better vehicle than this case for resolving that question.

1. In *Wages & White Lion*, the Fifth Circuit relied on multiple rationales in setting aside FDA's denial orders as arbitrary and capricious, and its decision created multiple circuit conflicts. See Pet. at 10-12, 22-23, *Wages & White Lion*, *supra* (No. 23-1038) (*Wages & White Lion* Pet.). In particular, the Fifth Circuit reasoned that (1) FDA had unfairly surprised manufacturers of e-cigarette products by changing applicable evidentiary standards after they had filed their applications, see *id.* at 14-17; (2) FDA had committed prejudicial error by declining to consider the applicants' marketing plans, see *id.* at 17-19; (3) FDA had arbitrarily disregarded differences among e-cigarette devices, see *id.* at 19-20; (4) FDA had improperly adopted a categorical ban on flavored e-cigarettes, see *id.* at 20-21; and (5) FDA had arbitrarily treated the flavored e-cigarette products at issue in *Wages & White Lion* differently than menthol-flavored products, see *id.* at 21-22.

The first question presented in this case, however, concerns only the first of the five issues in *Wages & White Lion*—namely, whether FDA unfairly surprised manufacturers by adopting a "new, heightened standard for evaluating already-pending" applications. Pet. i. Although the petition for a writ of certiorari alludes (at 28-29) to the second issue in *Wages & White Lion*—whether FDA's decision not to consider the applicant's

marketing plan constituted prejudicial error—this case does not present that issue. Here, FDA "did analyze [petitioner's] marketing plan and found it lacking." Pet. App. 38a. And the remaining issues involved in *Wages & White Lion* neither were discussed by the court below nor are encompassed by the first question presented in the petition for a writ of certiorari here.

Wages & White Lion is thus the only vehicle for deciding the full range of legal issues raised, and resolving the full range of circuit conflicts created, by the Fifth Circuit's decision in that case. Conversely, because the first question presented here involves an issue that is already presented in *Wages & White Lion*, there would be no need to grant plenary review in this case as well. Granting review in multiple cases, with FDA as petitioner in one case but respondent in the other, would needlessly result in duplicative briefing.

2. *Wages & White Lion* is also a better vehicle than this case because it involves e-cigarette products flavored to taste like fruit, candy, or dessert. See *Wages & White Lion* Pet. 6. All the cases on the opposite side of the relevant circuit conflicts, see *id.* at 13, likewise involve e-cigarette products with those sorts of flavors.[1]

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[1] See *Magellan Technology, Inc.* v. *FDA*, 70 F.4th 622, 625 (2d Cir. 2023) ("fruit and dessert flavors"), petition for cert. pending, No. 23-799 (filed Jan. 22, 2024); *Liquid Labs LLC* v. *FDA*, 52 F.4th 533, 537 (3d Cir. 2022) ("Berry Au Lait"); *Avail Vapor, LLC* v. *FDA*, 55 F.4th 409, 417 (4th Cir. 2022) ("fruit-and dessert-flavored"), cert. denied, 144 S. Ct. 277 (2023); *Gripum, LLC* v. *FDA*, 47 F.4th 553, 555 (7th Cir. 2022) ("candy, fruit, or baked goods"), cert. denied, 143 S. Ct. 2458 (2023); *Lotus Vaping Technologies, LLC* v. *FDA*, 73 F.4th 657, 665 (9th Cir. 2023) ("cinnamon candy"), petition for cert. pending, No. 23-871 (filed Feb. 9, 2024); *Electric Clouds, Inc.* v. *FDA*, 94 F.4th 950, 955 (10th Cir. 2024) ("Apple Pie") (emphasis

This case, by contrast, involves e-cigarette products flavored to taste like menthol. See Pet. App. 11a n.8. Although petitioner sought authorization to market fruit-flavored e-cigarette products as well, see p. 3, *supra*, "only the FDA's rejection of [the] menthol-flavored [e-cigarette products] is at issue" here, Pet. App. 11a n.8.

According to petitioner, however, the legal issues presented by menthol-flavored e-cigarettes differ from those presented by e-cigarettes with other flavors. Petitioner contends that "menthol-flavored [e-cigarette products], in particular, 'may be important to adult smokers seeking to transition away from cigarettes,' given that 'combustible cigarettes are still sold in menthol flavor,'" while "candy-, fruit-, and dessert-flavored [e-cigarette products] have no analogue in lawfully sold cigarettes." Pet. 1-2 (citation omitted). Petitioner also argues (Pet. 2) that "FDA never told menthol-flavored [e-cigarette] companies that they would need to" meet the standards applicable to "fruit-, candy-, and dessert-flavored [e-cigarettes]." And petitioner objects (Pet. 39) to "lumping [its menthol-flavored] products with all other companies' [e-cigarettes]."

Given that the circuit conflict on the first question presented arose in the context of e-cigarette products flavored to taste like fruit, candy, or dessert, the best vehicle for resolving that conflict is a case—*Wages & White Lion*—that involves those flavors. There is no reason for this Court to grant certiorari to resolve that conflict in the context of a different flavor (menthol) that, according to petitioner, raises different legal issues.

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omitted); *Prohibition Juice Co.* v. *FDA*, 45 F.4th 8, 15 (D.C. Cir. 2022) ("Cinnamon Pear").

3. Finally, the Fifth Circuit's opinion in *Wages & White Lion* extensively analyzed FDA's treatment of flavored e-cigarette products generally. See *Wages & White Lion Investments, L.L.C.* v. *FDA*, 90 F.4th 357, 371-388 (2024), petition for cert. pending, No. 23-1038 (filed Mar. 19, 2024). The Third Circuit's opinion in this case, by contrast, did not. Rather, as petitioner notes (Pet. 23-24), the Third Circuit's earlier decision in *Liquid Labs LLC* v. *FDA*, 52 F.4th 533, 537 (2022) foreclosed petitioner's contentions regarding FDA's treatment of flavored products generally. This Court may prefer to resolve the first question presented in a case in which that question was fully analyzed below, rather than in a case in which the question was pretermitted below because of circuit precedent.

B. The Second Question Presented Does Not Warrant This Court's Review At This Time

Petitioner separately asks this Court to decide (Pet. i) whether FDA acted arbitrarily and capriciously in evaluating menthol-flavored e-cigarette products in particular. That question does not warrant this Court's review at this time.

1. The court of appeals correctly rejected petitioner's menthol-specific arguments.

a. To begin, the court of appeals correctly rejected petitioner's contention (Pet. 35-36) that FDA unfairly surprised manufacturers of menthol-flavored e-cigarettes by changing the evidentiary standards applicable to those products after the manufacturers had filed their applications. FDA evaluated menthol-flavored products under "the same regulatory framework and evidentiary standard that the agency had applied previously to other non-tobacco flavored" products. Pet. App. 29a-30a. Because FDA "applied the same stand-

ard it had been applying since 2019 to other non-tobacco flavors," petitioner cannot properly claim "any unfair surprise." *Id.* at 33a.

Contrary to petitioner's contention (Pet. 35-36), the record does not support the contention that FDA had previously told e-cigarette manufacturers that it would apply a special evidentiary standard to menthol-flavored e-cigarettes. Petitioner principally relies (Pet. 32) on a 2020 guidance document announcing FDA's enforcement priorities. See FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry* 24 (Apr. 2020) (2020 Guidance) (footnote omitted). But "[t]hat document did not modify the FDA's guidance about the evidentiary standards" applicable to menthol-flavored products. Pet. App. 33a n.19. The document instead simply "set the order in which the FDA would launch enforcement actions." *Ibid.* FDA then "proceeded to apply [the same] framework to [e-cigarette] products in descending order of enforcement priority, starting with fruit-flavored [products] and eventually turning to" menthol-flavored products. *Id.* at 30a n.17.

Some of the data on which the 2020 Guidance rested, moreover, had become outdated by the time FDA acted on petitioner's applications. The 2020 Guidance cited a 2019 survey showing that—among 8th-, 10th-, and 12th-graders who used a particular brand of e-cigarettes—fewer than 6% preferred menthol-flavored products. See 2020 Guidance 15. "By 2022," however, National Youth Tobacco Survey data showed that, "among high schoolers who had used e-cigarettes in the previous thirty days, almost 27% had tried menthol, not far be-

hind mint (about 30%) and sweets (about 38%)." Pet. App. 17a. FDA also "had reason to believe that flavor preference data would trend in menthol's favor in the future." *Id.* at 18a. FDA thus did not unfairly surprise petitioners by applying a new evidentiary framework; instead, it just analyzed "new information under the same framework." *Id.* at 30a.

b. The court of appeals also correctly rejected petitioner's contention (Pet. 19) that FDA's "political leadership" improperly "overruled" the recommendations of career experts. As an initial matter, this Court has rejected the proposition that a politically accountable agency head acts arbitrarily by overruling experts at the agency. See *Department of Commerce* v. *New York*, 139 S. Ct. 2551, 2569-2571 (2019). A contrary rule, the Court has explained, would improperly "subordinat[e] the [agency head's] policymaking discretion to [career officials'] technocratic expertise." *Id.* at 2571.

Petitioner's argument in any event fails on its own terms. Petitioner cites internal documents showing that the Office of Science, a component of FDA's Center for Tobacco Products, was "preliminarily inclined to recommend approval" of petitioner's applications for authorization to market menthol-flavored products. Pet. App. 24a. But after the Center's Director asked the Office to reexamine the matter in light of concerns about the strength of the scientific evidence included in petitioner's applications, the Office reassessed its views and determined that it was "reasonable and consistent" to treat menthol-flavored products like other flavored products. *Ibid.* "Crediting [petitioner's] argument would penalize [FDA] for engaging in the 'ongoing dialogue' and deliberation that is supposed to be the hall-

mark of reasoned agency decision-making." *Id.* at 27a-28a (citation omitted).

c. Finally, petitioner contends (Pet. 38, 40) that FDA "discount[ed] entirely" "product-specific evidence showing that [petitioner's] products, in particular, do not appeal to youth," and that the agency improperly disregarded petitioner's plan to use "marketing and other strategies to mitigate potential youth usage." But as the court of appeals noted, FDA did not ignore the product-specific evidence; it instead considered that evidence and found it insufficient to show that the marketing of the products would be appropriate for the protection of the public health. See Pet. App. 34a-38a. In particular, FDA "did analyze [petitioner's] marketing plan and found it lacking." *Id.* at 38a.

Although "FDA did not weigh the evidence to [petitioner's] liking," Pet. App. 35a, that does not make its decision arbitrary and capricious. The scope of judicial review under the arbitrary-and-capricious standard is "narrow." *Department of Commerce*, 139 S. Ct. at 2569 (citation omitted). A court "may not substitute [its] judgment for that of the [agency]." *Ibid.* Nor may a court second-guess an agency's "weighing of risks and benefits." *Id.* at 2571. A court must instead "confine [itself] to ensuring that [the agency] remained 'within the bounds of reasoned decisionmaking.'" *Id.* at 2569 (citation omitted). The court of appeals correctly held that FDA stayed within those bounds here.

2. Petitioner argues (Pet. 33-35) that the decision below conflicts with the Fifth Circuit's decision in *R.J. Reynolds Vapor Co.* v. *FDA*, 65 F.4th 182 (2023). But that conflict does not warrant this Court's review because, as petitioner concedes (Pet. 34), "the Fifth Circuit issued *R.J. Reynolds* in a stay posture."

a. In *R.J. Reynolds*, FDA denied a manufacturer's applications for authorization to market menthol-flavored e-cigarettes. See 65 F.4th at 187. A motions panel of the Fifth Circuit granted the manufacturer a stay of FDA's denial order pending disposition of the petition for review. See *ibid.* The court held that the manufacturer had shown "likely success on the merits" of its claim that FDA had acted arbitrarily and capriciously in evaluating menthol-flavored e-cigarette products. *Id.* at 189; see *id.* at 191 ("[FDA's] positions are likely arbitrary and capricious"); *id.* at 192 ("[T]he Order is likely arbitrary, capricious, or otherwise unlawful."); *id.* at 194 ("[The manufacturer] is likely to show that the FDA has instituted a *de facto* ban on non-tobacco-flavored e-cigarettes.").

Although a motions panel of the Fifth Circuit granted a stay in *R.J. Reynolds*, no panel of that court has yet resolved the case on the merits. Rather, the court has stayed further proceedings in *R.J. Reynolds* pending this Court's resolution of the petition for a writ of certiorari in *Wages & White Lion*. See C.A. Doc. 314-2, *Wages & White Lion*, *supra*, No. 23-60037, at 3 (5th Cir. Feb. 15, 2024).

Any conflict between the Third Circuit's merits decision in this case and the Fifth Circuit's stay decision in *R.J. Reynolds* does not warrant this Court's review. A "motions panel [decision] does not bind the oral argument panel." *Firefighters' Retirement System* v. *Citco Group Ltd.*, 796 F.3d 520, 524 n.2 (5th Cir. 2015), cert. denied, 557 U.S. 1102 (2016). And a motions panel's prediction that a party is *likely* to succeed on the merits does not guarantee that it *will* succeed. (Indeed, in this case, petitioner obtained a stay but later lost on the merits. See p. 4, *supra*.) The motions panel's provi-

sional decision in *R.J. Reynolds* thus does not represent the Fifth Circuit's definitive resolution of the issues and, accordingly, does not establish a circuit conflict warranting this Court's review.

Before the en banc Fifth Circuit issued its decision in *Wages & White Lion*, a motions panel of that court had similarly granted a stay based on its conclusion that FDA had likely acted arbitrarily and capriciously in evaluating flavored e-cigarette products. See *Wages & White Lion Investments, L.L.C.* v. *FDA*, 16 F.4th 1130, 1134 (2021). And just last year, this Court denied two certiorari petitions asserting circuit conflicts with the stay ruling in *Wages & White Lion*. See *Avail Vapor, LLC* v. *FDA*, 144 S. Ct. 277 (2023); *Gripum, LLC* v. *FDA*, 143 S. Ct. 2458 (2023); see also Br. in Opp. at 11, *Avail Vapor*, *supra* (No. 22-1112); Br. in Opp. at 8-9, *Gripum*, *supra* (No. 22-708). Any conflict between the decision below and the stay ruling in *R.J. Reynolds* likewise does not warrant this Court's review at this time.

b. Petitioner's contrary arguments lack merit. Petitioner argues (Pet. 34) that, although "the Fifth Circuit issued *R.J. Reynolds* in a stay posture," that court has since cited the decision "as circuit precedent" in other cases. But in the cases that petitioner cites, the Fifth Circuit relied on *R.J. Reynolds* for uncontroversial, general principles of administrative law: the principle that an agency "cannot 'surprise' a party by penalizing it for 'good-faith' reliance on the agency's prior positions," *Inhance Technologies, L.L.C.* v. *EPA*, 96 F.4th 888, 895 (2024) (quoting *R.J. Reynolds*, 65 F.4th at 189), and the principle that an agency that is changing position "must at least display awareness" that it is doing so, *Chamber of Commerce of United States* v. *SEC*, 85 F.4th 760, 777 n.23 (2023) (quoting *R.J. Reynolds*, 65

F.4th at 189). Petitioner cites no case in which the Fifth Circuit has treated *R.J. Reynolds* as binding precedent on the question presented here: whether FDA has acted arbitrarily and capriciously in denying applications for authorization to market menthol-flavored e-cigarette products.

Petitioner also complains (Pet. 44) that, because the Fifth Circuit issued a stay in *R.J. Reynolds*, parties that have challenged their denial orders in the Fifth Circuit can "continue selling their menthol products," while other parties (such as petitioner) cannot. But the Third Circuit *granted* petitioner's motion for a stay of FDA's order pending the disposition of the petition for review. See p. 4, *supra*. It also granted petitioner's motion for a stay of its mandate pending disposition of the petition for a writ of certiorari to which this brief responds. See pp. 5-6, *supra*. Petitioner thus errs in suggesting that holding this petition would put it at an unfair disadvantage relative to competitors that have filed petitions for review in the Fifth Circuit.

Finally, petitioner observes (Pet. 44) that, in *R.J. Reynolds*, the Fifth Circuit read the Act's venue provision to mean that an out-of-circuit manufacturer could file a petition for review in that circuit so long as it is joined by an in-circuit retailer that sells its products. That broad reading, petitioner continues (*ibid.*), means that the Fifth Circuit's stay orders have "nationwide" effects. But the government has filed a separate petition for a writ of certiorari in which it has challenged the Fifth Circuit's reading of the venue provision. See Pet., *FDA* v. *R.J. Reynolds Vapor Co.*, No. 23-1187 (filed May 2, 2024). Concerns raised by the Fifth Cir-

cuit's reading of the venue provision are best addressed by granting that petition, not by granting this one.[2]

CONCLUSION

This Court should hold the petition for a writ of certiorari pending the resolution of *FDA* v. *Wages & White Lion Investments, L.L.C.*, petition for cert. pending, No. 23-1038 (filed Mar. 19, 2024), and should then dispose of the petition as appropriate.

Respectfully submitted.

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MAY 2024

[2] The government's petition for a writ of certiorari on the venue issue in *R.J. Reynolds* is consistent with its opposition to certiorari on the merits issue here. The Fifth Circuit definitively addressed venue in *R.J. Reynolds*, holding that "venue *is* proper in this circuit." 65 F.4th at 188 (emphasis added). But it did not definitively address the merits, concluding only that FDA's action was "*likely* arbitrary and capricious." *Id.* at 191 (emphasis added).