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

REPLY BRIEF FOR THE PETITIONER

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In the decision below, the en banc Fifth Circuit held that the Food and Drug Administration (FDA) acted arbitrarily and capriciously in denying respondents' applications for authorization to market flavored e-cigarette products. See Pet. App. 2a-4a. Respondents defend (Br. in Opp. 22-29) that decision on the merits, but they do not dispute that it conflicts with the decisions of seven other courts of appeals upholding FDA's denial of similar applications. Nor do they deny that the decision has significant practical consequences. They note (*id.* at 29-30) that other pending certiorari petitions present the same question that is presented here. But this case is the only vehicle for addressing the full range of issues raised—and resolving the full range of circuit conflicts created—by the Fifth Circuit's decision. This Court should grant the petition for a writ of certiorari.

A. The Fifth Circuit's Decision Was Wrong

Respondents primarily argue (Br. in Opp. 22-29) that the Fifth Circuit's decision was correct. A complete discussion of the merits can await full briefing and argument. For present purposes, it suffices to note that other courts of appeals have uniformly rejected the legal theories that the Fifth Circuit invoked and that respondents now defend. See Pet. 13, 22-23.

To begin, seven other courts of appeals have rejected the argument that FDA "changed its position on the authorization requirements for [e-cigarette products] without giving [applicants] fair notice and without considering [their] reliance interests." Br. in Opp. 22 (emphasis omitted); see Pet. 14-15. Respondents claim (Br. in Opp. 23) that FDA surprised applicants by requiring them to submit studies substantiating the claimed benefit. In reality, however, the statutory text and FDA's guidance made clear from the beginning that an applicant was required to submit *either* "well-controlled investigations" *or* other "valid scientific evidence" in support of their claims. 21 U.S.C. 387j(c)(5)(A) and (B); see, *e.g.*, C.A. App. A299 (2019 guidance document stating that applicants would not need to provide "long-term studies" if they could provide other forms of "valid scientific information"); *Prohibition Juice Co.* v. *FDA*, 45 F.4th 8, 21 (D.C. Cir. 2022) ("[FDA's] 2019 Guidance said that randomized controlled trials or longitudinal studies would not be necessary if applicants submitted similarly rigorous 'valid scientific evidence.'") (citation omitted). FDA denied respondents' applications because respondents failed to submit either form of evidence. See Pet. 15-16.

Similarly, six other courts of appeals have rejected the contention that "FDA committed prejudicial error"

by declining to evaluate marketing plans, where the plans replicated measures that the agency had already evaluated and rejected as inadequate. Br. in Opp. 26 (emphasis omitted); see Pet. 18. Respondents suggest (Br. in Opp. 27) that their plans differ from others that FDA has rejected. As the merits panel in this case noted, however, "nothing in [respondents'] briefing * * * indicates that their marketing plan was in fact unique." Pet. App. 124a. Respondents' plan merely "called for their products to be only sold in age-gated vape and specialty tobacco shops and through age-gated online sales." *Ibid.* "But FDA has already explained that such attempts do *not* work." *Ibid.*; see, *e.g.*, *Avail Vapor, LLC* v. *FDA*, 55 F.4th 409, 426 (4th Cir. 2022), cert. denied, 144 S. Ct. 277 (2023).

Six courts of appeals have likewise rejected the claim that FDA has ignored "the differences" among types of e-cigarette devices. Br. in Opp. 3; see Pet. 19-20. Respondents emphasize a 2020 guidance document in which FDA announced that it would prioritize enforcement against "cartridge-based" flavored e-cigarettes because those devices were popular among youth at that time. Br. in Opp. 12 (citation omitted). But FDA has explained that "youth preferences for different device types are 'fluid,'" that "youth readily shift among devices," and that flavors play a "'fundamental role'" in driving appeal to youth regardless of device type. *Prohibition Juice*, 45 F.4th at 26 (citations omitted). "FDA supported its conclusion with substantial evidence," and a court has "no basis to second-guess it." *Ibid.*

One court of appeals has also rejected the claim that FDA has improperly denied marketing-authorization applications "*en masse*." Br. in Opp. 17; see Pet. 20. In fact, FDA has accorded individualized consideration to

each of the applications that has come before it. See *Gripum, LLC* v. *FDA*, 47 F.4th 553, 559 (7th Cir. 2022), cert. denied, 143 S. Ct. 2458 (2023). And the fact that FDA has reached similar results in evaluating different manufacturers' flavored e-cigarette products, see Br. in Opp. 17, shows that it is applying the statute consistently, not that it has adopted a de facto ban on such products.

Finally, respondents do not attempt to defend the Fifth Circuit's holding that FDA arbitrarily treated menthol-flavored e-cigarettes differently from other flavored e-cigarettes. See Pet. 21-22. Respondents had disavowed that contention in the court of appeals, see *ibid.*, and they do not retreat from that disavowal here.

B. The Question Presented Warrants This Court's Review

Respondents do not meaningfully dispute that the question presented warrants this Court's review. They concede (Br. in Opp. 30) that the Fifth Circuit's decision created multiple "circuit splits." See Pet. 22-23. They do not dispute that the legal issues raised by this case frequently recur. See Pet. 24. And they do not deny that the Fifth Circuit's decision has significant practical consequences. See Pet. 25-26.*

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* Our petition for a writ of certiorari in this case explained (at 25-26) that the Fifth Circuit's erroneous interpretation of the applicable venue statute has magnified the practical consequences of its decision. We have since filed a separate petition for a writ of certiorari seeking review on the venue issue. See *FDA* v. *R.J. Reynolds Vapor Co.*, No. 23-1187, petition for cert. pending (filed May 2, 2024). The venue issue in *R.J. Reynolds* and the merits issue presented in this case are distinct; neither case depends on the other. The pendency of the certiorari petition in *R.J. Reynolds* accordingly provides no reason for this Court to delay its consideration of the certiorari petition in this case. Nor would it be necessary for the cases to be briefed and argued in tandem.

Respondents seek (Br. in Opp. 29-30) to minimize the significance of the circuit conflicts by asserting that "the (now vacated) merits panel decision in this case started a domino effect in some other circuits that benefited FDA." Far from simply citing and following the panel's initial decision in this case, however, other courts of appeals issued extensive opinions analyzing the lawfulness of FDA's actions. See, *e.g.*, *Prohibition Juice*, 45 F.4th at 20-26. In any event, regardless of whether the circuit conflicts resulted from a "domino effect," Br. in Opp. 30, respondents do not dispute that the conflicts are now entrenched. Nor do they dispute that this Court's intervention is necessary to resolve those conflicts.

Respondents also quibble (Br. in Opp. 27) with our observation that the Fifth Circuit created a 6-1 circuit conflict about whether FDA committed prejudicial error by declining to consider an applicant's marketing plans. See Pet. 22. Respondents argue (Br. in Opp. 27) that the Eleventh Circuit, too, has concluded that FDA committed prejudicial error by declining to evaluate marketing plans. See *Bidi Vapor LLC* v. *FDA*, 47 F.4th 1191, 1206 (2022). But as we have explained (Pet. 19), the Eleventh Circuit held that FDA had failed to consider "novel" marketing restrictions that the agency had not previously encountered. By contrast, this case and the other cases in the circuit conflict involve familiar types of restrictions that FDA had previously considered and rejected as inadequate. Respondents insist (Br. in Opp. 29) that the Eleventh Circuit's decision did not turn on the novelty of the plans, but that interpretation conflicts with the plain language of the court's opinion. See, *e.g.*, *Bidi Vapor*, 47 F.4th at 1205 ("[The plans] included measures not specifically mentioned in

[FDA's previous guidance]."); *id.* at 1206 ("The crux of our disagreement with the dissent is whether it is the role of this Court or of the Administration to consider the novel marketing and sales-access-restriction plans submitted by the tobacco companies."). In all events, respondents' argument would show only that the circuit conflict on the marketing-plan issue is even deeper than we have claimed—further reinforcing that the petition should be granted.

The amicus briefs supporting certiorari confirm that the question presented warrants this Court's review. Amici Public Health, Medical, and Community Groups explain (Br. 6-17) that the decision below, if allowed to stand, would seriously impair FDA's efforts to protect young people from the harmful effects of e-cigarettes. Other amici explain that the e-cigarette industry, too, has a strong interest in the Court's resolution of the question presented. See Logic Technology Amicus Br. 6-19; Vaping Industry Stakeholders Amicus Br. 4-22.

C. This Case Is The Best Vehicle For Resolving The Question Presented

1. This case is an ideal vehicle for resolving the question presented, and respondents provide no good reason to think otherwise. Respondents do not deny that the government preserved its contentions in the court of appeals, that the court passed on those contentions, and that no threshold obstacle would preclude this Court from reaching those contentions.

Respondents argue (Br. in Opp. 30) that, as "small business applicants" that "have had to undertake the time and expense of both a merits panel hearing and an en banc rehearing," they should not be required to bear the burden of Supreme Court proceedings as well. But respondents, whose businesses have generated "$15 to

20 million [in] annual revenues," Pet. App. 140a (Jones, J., dissenting), do not explain why they deserve a special exemption from litigating in this Court. Respondents, moreover, were the ones who filed a petition for review and who then filed a petition for rehearing en banc—seeking the very decision that created the multiple circuit conflicts warranting this Court's review. See Pet. 10. Having made those choices, they are ill-positioned to complain about the burdens of the proceedings in this Court necessary to resolve those conflicts.

2. Respondents identify (Br. in Opp. 30) two other pending cases that present the same question as this case: *Magellan Technology, Inc.* v. *FDA*, petition for cert. pending, No. 23-799 (filed Jan. 22, 2024), and *Lotus Vaping Technologies, LLC* v. *FDA*, petition for cert. pending, No. 23-871 (filed Feb. 9, 2024). But our certiorari petition in this case and our certiorari responses in *Magellan* and *Lotus Vaping* have explained why this case is the best vehicle for resolving the question presented. See Pet. 26; Resp. Br. at 5-6, *Magellan*, *supra* (No. 23-799); Resp. Br. at 5-6, *Lotus Vaping*, *supra* (No. 23-871). The Fifth Circuit relied on multiple rationales, and created multiple circuit conflicts, in holding that FDA's denial of respondents' applications was arbitrary and capricious. See *ibid.* But only some of those rationales are at issue in *Magellan* and *Lotus Vaping*. See *ibid.* This case is thus the only vehicle for deciding all the relevant issues and resolving all the circuit conflicts created by the Fifth Circuit's decision. See *ibid.* Respondents do not address, much less dispute, those points. See Br. in Opp. 29-30.

The petitioner in *Lotus Vaping* argues that its case would be "a proper vehicle for the Court to resolve the circuit conflict," but that is incorrect. Cert. Reply Br.

at 1, *Lotus Vaping*, *supra* (No. 23-871). The Fifth Circuit relied on five rationales in setting aside FDA's denial orders as arbitrary and capricious, but in *Lotus Vaping*, the Ninth Circuit addressed only three of those issues, and the certiorari petition focused on only two of them. See Resp. Br. at 5, *Lotus Vaping*, *supra* (No. 23-871). The petitioner in that case now claims, in its reply brief, that the third contention "is subsumed" under its other arguments. Cert. Reply Br. at 1, *Lotus Vaping*, *supra* (No. 23-871). But this Court normally does not consider issues that are raised for the first time in a reply brief. See, *e.g.*, *Republic of Argentina* v. *NML Capital, Ltd.*, 573 U.S. 134, 140 n.2 (2014). Even accepting the reply's characterization, moreover, *Lotus Vaping* would still present only three of the five issues raised by the Fifth Circuit's decision here. *Lotus Vaping* thus would not enable this Court to resolve all the circuit conflicts created by the decision below.

3. Amicus Logic Technology asks this Court to grant its own certiorari petition in *Logic Technology Development, LLC* v. *FDA*, No. 23-1125 (filed Apr. 15, 2024), alongside the certiorari petition in this case. As we have explained in *Logic*, the Court should reject that request. See Resp. Br. at 6-17, *Logic*, *supra* (No. 23-1125).

Logic presents two questions: (1) whether FDA has acted arbitrarily and capriciously in evaluating applications to market flavored e-cigarette products in general, and (2) whether it has acted arbitrarily and capriciously in evaluating applications to market menthol-flavored e-cigarette products in particular. See Resp. Br. at 6, *Logic*, *supra* (No. 23-1125). The first question in *Logic* overlaps with the question presented here, but this case is a better vehicle for resolving it. See *id.* at 7. *Logic*, like *Magellan* and *Lotus Vaping*, involves only a subset

of the legal issues raised (and circuit conflicts created) by the Fifth Circuit's decision here. See *id.* at 7-8. In addition, all the cases in the relevant circuit conflicts (including this case) involve e-cigarette products flavored to taste like fruit, candy, or dessert. See *id.* at 8 & n.1. *Logic*, by contrast, involves menthol-flavored products, which (according to the petitioner in that case) raise distinct legal issues. See *id.* at 9.

The second question in *Logic*, which concerns FDA's treatment of menthol-flavored products in particular, does not warrant this Court's review at this time. See Br. in Opp. at 10-17, *Logic*, *supra* (No. 23-1125). In both its certiorari petition in *Logic* and its amicus brief here, Logic asserts a conflict with the Fifth Circuit's decision in *R.J. Reynolds Vapor Co.* v. *FDA*, 65 F.4th 182 (2023). See Pet. at 33-35, *Logic*, *supra* (No. 23-1125); Logic Amicus Br. 17. But as we explained in *Logic*, that decision was issued by a motions panel, concerned only a motion for a stay, and did not definitively resolve the merits. See Resp. Br. at 14, *Logic*, *supra* (No. 23-1125). In all events, regardless of what this Court does in *Logic*, it should grant certiorari in this case.

* * * * *

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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