No. 24-474

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, PETITIONER

v.

SWT GLOBAL SUPPLY, INC., 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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Respondents concede (Br. in Opp. 4) that, in the decision below, the court of appeals relied on its earlier decision in *Wages & White Lion Investments, L.L.C.* v. *FDA*, 90 F.4th 357 (5th Cir.) (en banc), cert. granted, 144 S. Ct. 2714 (2024), in holding that the Food and Drug Administration (FDA) acted arbitrarily and capriciously in denying respondents' applications for marketing authorization. They also acknowledge (Br. in Opp. 10-11) that, if this Court "reverses [the] judgment" in *FDA* v. *Wages & White Lion Investments, L.L.C.*, No. 23-1038 (argued Dec. 2, 2024), "remanding [these] cases * * * for reconsideration by the Fifth Circuit in the first instance would be in keeping with this Court's normal practice."

Respondents nonetheless contend (Br. in Opp. 9) that this Court should deny certiorari rather than hold the petition pending resolution of *Wages* because "dis-

tinctions between Respondents' marketing plans and those proposed in *Wages* provide an independent basis for affirmance of the Fifth Circuit's judgment." Specifically, they argue (*id.* at 9-10) that their marketing plans contain novel measures that FDA had not previously encountered and that, as a result, FDA's decision not to consider those plans would be prejudicial even under the government's theory in *Wages*. See Gov't Br. at 35, *Wages*, *supra* (No. 23-1038) ("FDA's decision not to evaluate a marketing plan is harmless if the plan replicates measures that the agency has considered and rejected.").

That argument lacks merit. The court of appeals ruled for respondents solely on the ground that FDA acted arbitrarily by denying respondents' applications for marketing authorization "based on the absence of long-term clinical studies." Pet. App. 6a. The court saw "no basis to distinguish this case from *Wages*," in which it had invoked the same rationale (alongside multiple other rationales) in holding that the agency had acted arbitrarily. *Ibid.* The court did not, however, discuss FDA's decision not to consider respondents' marketing plans. See *id.* at 5a-6a. Much less did the court analyze the contents of the plans or rely on the alternative rationale that respondents now invoke.

The government disputes respondents' assertion that their marketing plans differ materially from others that FDA has considered and rejected. See, *e.g.*, 21-60762 Gov't C.A. Br. 41 (arguing that respondents "do not claim to have proposed advertising and sales access measures different from those that FDA previously found inadequate"). This Court, however, need not resolve that issue in the first instance. Rather, as respondents elsewhere explain (Br. in Opp. 11), "the Court of

Appeals should pass first upon any factual or legal distinctions in light of the opinion in *Wages*." Respondents assert (*id.* at 9) that "FDA has waived any challenge to [respondents' proposed alternative] basis for the judgment below because it has not addressed Respondents' marketing plans in its petition." But the government has no obligation to anticipate and preemptively address alternative theories that the court of appeals never invoked.

Even if respondents were right that their marketing plans propose novel restrictions—or even if this Court in *Wages* were to reject the government's argument that FDA's decision not to consider marketing plans was harmless—the Court should still vacate the court of appeals' judgment. The court of appeals set aside FDA's orders based on its conclusion that "FDA pulled a surprise switcheroo," Pet. App. 5a, not based on a conclusion that FDA had acted unlawfully by failing to consider respondents' marketing plans. That choice of rationale affects the nature of the administrative proceedings on remand to the agency—for instance, by affecting whether FDA would need to re-evaluate aspects of the applications apart from the marketing plans.

Respondents also contend (Br. in Opp. 11-12) that their cases differ from *Wages* in other respects. See, *e.g.*, *id.* at 11 (asserting that respondents' fair-notice claim differs from the fair-notice claim in *Wages* because it focuses on "change in potential comparator products" rather than "change of study *type*"); *ibid.* (arguing that "Respondents' motion to supplement the record in the Fifth Circuit * * * might prove important following a remand"). But the court of appeals did not rely on those alternative rationales either; rather, as discussed above, it ruled in respondents' favor "for the

reasons amply explained by the en banc court in *Wages*." Pet. App. 6a. Respondents are thus correct in conceding (Br. in Opp. 12) that those alternative theories "should be addressed in the first instance by the Court of Appeals."

* * * * *

The Court should hold the petition for a writ of certiorari pending its resolution of *FDA* v. *Wages & White Lion Investments, L.L.C.*, No. 24-1038 (argued Dec. 2, 2024), and then dispose of the petition as appropriate in light of that decision.

Respectfully submitted.

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