No.

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL., PETITIONERS

v.

R.J. REYNOLDS VAPOR CO., ET AL.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION 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. If FDA denies an application for authorization, "any person adversely affected by such * * * denial may file a petition for judicial review of such * * * denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business." 21 U.S.C. 387*l*(a)(1). The U.S. Court of Appeals for the Fifth Circuit has determined that a manufacturer may seek judicial review in that circuit even if it neither resides nor has its principal place of business there, so long as its petition is joined by a seller of its products, such as a gas station or convenience store, based in the circuit. The question presented is:

Whether a manufacturer may file a petition for review in a circuit (other than the D.C. Circuit) where it neither resides nor has its principal place of business, if the petition is joined by a seller of the manufacturer's products that is located within that circuit.

PARTIES TO THE PROCEEDING

Petitioners (respondents below) are the Food and Drug Administration (FDA); Robert Califf, in his official capacity as Commissioner of FDA; the Department of Health and Human Services; and Xavier Becerra, in his official capacity as Secretary of Health and Human Services. Respondents (petitioners below) are R.J. Reynolds Vapor Company; RJR Vapor Company, L.L.C.; Avail Vapor Texas, L.L.C.; and Mississippi Petroleum Marketers and Convenience Stores Association.

RELATED PROCEEDING

United States Court of Appeals (5th Cir.):

R.J. Reynolds Vapor Co. v. *FDA*, No. 23-60545 (Feb. 2, 2024)

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The Solicitor General, on behalf of the petitioners, respectfully petitions for a writ of certiorari to review the order of the United States Court of Appeals for the Fifth Circuit in this case.

OPINIONS BELOW

The order of the court of appeals (App., *infra*, 1a-8a) is unreported.

JURISDICTION

The order of the court of appeals was entered on February 2, 2024. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISION INVOLVED

The pertinent statutory provision is reproduced in the appendix. App., *infra*, 24a.

STATEMENT

1. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or Act), Pub. L. No. 111-31, Div. A, 123 Stat. 1776. The Act imposes special restrictions on the marketing of "'new tobacco products'"—that is, tobacco products that were not commercially marketed in the United States as of February 15, 2007. 21 U.S.C. 387j(a)(1). A manufacturer may introduce a new tobacco product into interstate commerce only if it obtains authorization from the Secretary of Health and Human Services. See 21 U.S.C. 387j(c)(2)(A). The Secretary exercises that authority through the Food and Drug Administration (FDA). See 21 U.S.C. 393(d)(2).

The Act provides that "any person adversely affected" by the "denial of an application" for marketing authorization "may file a petition for judicial review" within 30 days after the denial. 21 U.S.C. 387*l*(a)(1)(B). The petition must be filed "with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business." 21 U.S.C. 387*l*(a)(1). The court must review the agency action in accordance with the judicial-review provisions of the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq.* See 21 U.S.C. 387*l*(b).

In 2016, FDA promulgated a rule announcing that it would regulate electronic nicotine delivery systems, more commonly known as e-cigarettes or vapes, 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 Tobacco Products; Final Rule*, 81

Fed. Reg. 28,974, 29,028-29,044 (May 10, 2016). An e-cigarette is a battery-powered device that heats a liquid containing nicotine and other substances, converting the liquid into an aerosol (a suspension of small airborne droplets) that the user inhales. See Centers for Disease Control and Prevention (CDC), U.S. Dep't of Health and Human Services, *E-Cigarette, or Vaping, Products Visual Dictionary* 7. E-cigarettes 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. Respondent R.J. Reynolds Vapor Co. (Reynolds) manufactures e-cigarette products under the brand name Vuse. See App., *infra*, 13a. Reynolds is incorporated, and thus resides, in North Carolina, and it maintains its principal place of business in Winston-Salem, North Carolina. See R.J. Reynolds Vapor Co., *Business Corporation Annual Report, F.Y. 2022*, at 1 (Jan. 30, 2023).

Reynolds applied for authorization to market three sets of flavored e-cigarette products: Vuse Vibe, Vuse Solo, and Vuse Alto. We refer to the Fifth Circuit case concerning Vuse Vibe (No. 23-60037) as *Vibe*, the case concerning Vuse Solo (No. 23-60128) as *Solo*, and the case concerning Vuse Alto (No. 23-60545) as *Alto*. This petition for a writ of certiorari seeks review of an order issued in *Alto*, but we describe the proceedings in all three cases because they provide relevant context.

FDA denied all three sets of applications. See *Vibe* C.A. Pet. for Review, Ex. A at 1-4 (Jan. 24, 2023); *Solo* C.A. Pet. for Review, Ex. A 1-4 (Mar. 17, 2023); App., *infra*, 9a-23a. The Act permits FDA to grant marketing authorization only if the manufacturer shows that the

marketing of the product is "appropriate for the protection of the public health." 21 U.S.C. 387j(a)(2)(A). FDA found that Reynolds had failed to make that showing. See *Vibe* C.A. Pet. for Review, Ex. A at 1; *Solo* C.A. Pet. for Review, Ex. A at 1; App., *infra*, 9a-10a.

3. Reynolds filed three petitions for review, which the court of appeals later consolidated. See *Vibe* C.A. Doc. 231 (Oct. 19, 2023).

a. Under the Act, Reynolds could have filed a petition for review in either the Fourth Circuit (where it is based) or the D.C. Circuit. See App., *infra*, 7a (Higginson, J., dissenting). But "[t]hose two courts ha[d] already ruled on questions central to these cases in a manner that is adverse to Reynolds' position." *Ibid.* In particular, Reynolds claims that FDA acted arbitrarily and capriciously by, among other things, changing the evidentiary standards for flavored e-cigarette products after manufacturers had submitted their applications. See *Vibe* C.A. Doc. 62, at 12-18 (Feb. 8, 2023). The Fourth and D.C. Circuits had previously rejected similar claims. See *Avail Vapor,* 55 F.4th at 422 (4th Cir.); *Prohibition Juice Co.* v. *FDA*, 45 F.4th 8, 21 (D.C. Cir. 2022).

Reynolds filed its petitions for review in the Fifth Circuit instead. See App., *infra*, 3a. A panel of that court had previously rejected an arbitrary-and-capricious challenge to an FDA denial order in *Wages & White Lion Investments, L.L.C.* v. *FDA*, 41 F.4th 427, 439 (2022), but by the time Reynolds filed its petitions for review, the Fifth Circuit had vacated that decision and

granted rehearing en banc, see *Wages & White Lion Investments, L.L.C.* v. *FDA*, 58 F.4th 233 (2023).*

Each of Reynolds' petitions for review was joined by three other entities: (1) RJR Vapor Co., LLC, a North Carolina company that sells Vuse products online; (2) Avail Vapor Texas, LLC (Avail), a Texas company that operates a retail store selling Vuse products; and (3) the Mississippi Petroleum Marketers and Convenience Stores Association (Convenience Stores Association), a Mississippi association of gas stations and convenience stores, some of which sell Vuse products. See *Vibe* C.A. Doc. 1-1, at 1-3; *Solo* C.A. Doc. 1-1, at 1-3; *Alto* C.A. Doc. 1, at 1-4; RJR Vapor Co., LLC, *Limited Liability Company Annual Report, 2023*, at 1 (Jan. 30, 2023). Reynolds and the other entities, respondents here, argued that venue was proper because Avail and the Convenience Stores Association were both based in the Fifth Circuit. See *Vibe* C.A. Doc. 1, at 3; *Solo* C.A. Doc. 1, at 3 *Alto* C.A. Doc. 1, at 3.

b. In *Vibe*, respondents moved to stay FDA's denial order pending resolution of the petition for review. See *R.J. Reynolds Vapor Co.* v. *FDA*, 65 F.4th 182, 188 (5th Cir. 2023). A motions panel granted the stay in a published opinion. See *id.* at 189.

The Fifth Circuit first held that "venue is proper in this circuit" even though Reynolds neither resided nor had its principal place of business there. *Reynolds*, 65 F.4th at 188. In the court's view, it was enough that "*a*

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* The en banc Fifth Circuit later ruled in favor of the e-cigarette manufacturers on the arbitrary-and-capricious challenge. See *Wages & White Lion Investments, L.L.C.* v. *FDA*, 90 F.4th 357, 386 (2024). FDA has sought certiorari to review that decision. See *FDA* v. *Wages & White Lion Investments, L.L.C.*, No. 23-1038 (filed Mar. 19, 2024).

petitioner ha[d] its 'principal place of business'" in the circuit. *Ibid.* (emphasis added). The court stated in an accompanying footnote that the Convenience Stores Association "is incorporated in and has its principal place of business in Mississippi." *Id.* at 188 n.5.

The Fifth Circuit then determined that Reynolds was likely to prevail on the merits of its arbitrary-and-capricious challenge, see *Reynolds*, 65 F.4th at 189-194, and that the equities supported granting a stay, see *id.* at 194-195. The court acknowledged that the Fourth and D.C. Circuit had rejected similar arbitrary-and-capricious claims, but dismissed their decisions as "unpersuasive." *Id.* at 194 n.11.

The government filed a petition for rehearing en banc, in which it specifically challenged the panel's ruling on the venue issue. See *Vibe* C.A. Doc. 145, at 21-25 (Apr. 7, 2023). The Fifth Circuit denied that en banc petition. See *Vibe* C.A. Doc. 312-1, at 1-2 (Feb. 6, 2024). The government also filed a motion to transfer the petition for review to the D.C. Circuit, but the Fifth Circuit denied that motion in an order without accompanying reasoning. See *Vibe* C.A. Doc. 220-2, at 1-2 (June 27, 2023).

c. In *Solo*, the Fifth Circuit issued a similar order denying the government's motion to transfer the petition for review to the D.C. Circuit. See *Solo* C.A. Doc. 137-2, at 1-2 (June 27, 2023). The court also issued an order granting respondents' motion for a stay of FDA's denial order pending review. See *Solo* C.A. Doc. 221-2, at 1-3 (Feb. 2, 2024).

d. Finally, in *Alto*, the government moved to dismiss the petition for review or to transfer it to the D.C. Circuit or Fourth Circuit. See *Alto* C.A. Doc. 43, at 23 (Oct.

18, 2023). The Fifth Circuit denied the motion in an unpublished order. See App, *infra*, 1a-8a.

The Fifth Circuit stated that it "remain[ed] bound by [its] holding in the published opinion that venue is proper in this circuit" and that "[s]tare decisis governs venue here." App., *infra*, 4a. The court also stated that, because the Tobacco Control Act allows "any person adversely affected" to challenge the denial of an application for marketing authorization, e-cigarette sellers may "challenge FDA decisions that affect them." *Ibid.* (citation and emphasis omitted).

Judge Higginson dissented. See App., *infra*, 6a-8a. He reasoned that the Fifth Circuit's interpretation of the Act effectively nullified its venue limitations. See *id.* at 6a-7a. He also stated that the court's "expansive reading of venue cannot seem to be reconciled with other provisions of the [Act]." *Id.* at 7a.

In a separate order, the Fifth Circuit granted respondents' motion to stay FDA's denial order pending resolution of the petition for review. See *Alto* C.A. Doc. 133, at 1-3 (Feb. 2, 2024). Judge Higginson dissented from that order as well. See *id.* at 3 n.*.

REASONS FOR GRANTING THE PETITION

The Tobacco Control Act provides for judicial review of an FDA order denying a manufacturer's application for authorization to market a tobacco product, but only in the D.C. Circuit or the circuit where the party seeking review resides or has its principal place of business. See 21 U.S.C. 387*l*(a)(1). Any such review is limited to a petition filed by a person "adversely affected" by the order, which the text and structure of the Act demonstrate is limited to the person whose application for marketing authorization was denied by FDA. Yet in the decision below, the Fifth Circuit held that an e-cigarette

manufacturer that neither resides nor maintains its principal place of business in that circuit may seek review there, so long as its petition for review is joined by a local gas station or convenience store that sells its products. Relying on that holding, other out-of-circuit manufacturers have begun to file petitions for review in the Fifth Circuit using the same tactic. The Fifth Circuit's decision permits retail sellers of a tobacco product who have no right of judicial review under the Act to nevertheless gain review; effectively nullifies the Act's limits on venue; facilitates blatant forum shopping; and undermines the precedents of other circuits. This Court should grant review and reverse the Fifth Circuit's order in *Alto* denying the motion to dismiss or transfer.

A. The Decision Below Is Wrong

The Tobacco Control Act's judicial-review provision states:

> Not later than 30 days after—
>
> (A) the promulgation of a regulation under [21 U.S.C. 387g] establishing, amending, or revoking a tobacco product standard; or
>
> (B) a denial of an application under [21 U.S.C. 387j(c)],
>
> any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

21 U.S.C. 387*l*(a)(1). The Fifth Circuit has read that provision to mean that an out-of-circuit manufacturer

may obtain judicial review of an FDA denial order in that circuit, so long as its petition for review is joined by a local seller of its products. That reading is wrong on multiple levels.

1. To begin, the Fifth Circuit erred in holding that a *retail seller* of tobacco products has a statutory right to seek judicial review of an FDA order denying a *manufacturer's* application for marketing authorization for a new tobacco product. Under the Act, only the applicant may challenge FDA's denial of its application.

The Act provides that a "person adversely affected" may seek judicial review of a denial order. 21 U.S.C. 387*l*(a)(1). The term "'adversely affected,'" like its close cousin "'aggrieved,'" is a "term of art" with "a long history in federal administrative law." *Director, Office of Workers' Compensation Programs* v. *Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 126 (1995). This Court has read those and similar terms to mean that a person may sue only if its interests "fall within the zone of interests protected by the law invoked." *Lexmark International, Inc.* v. *Static Control Components, Inc.*, 572 U.S. 118, 129 (2014) (citation omitted); see, *e.g.*, *Thompson* v. *North American Stainless, L.P.*, 562 U.S. 170, 177-178 (2011). The "breadth of the zone of interests" depends on "the provisions of law at issue." *Bennett* v. *Spear*, 520 U.S. 154, 163 (1997). As a result, "what comes within the zone of interests of a statute for purposes of * * * the 'generous review provisions' of the APA may not do so for other purposes." *Ibid.* (citation omitted). Ultimately, discerning the scope of the zone of interests involves inferring "the probable legislative intent" from the structure of "the statutory scheme." *Newport News*, 514 U.S. at 127 (citation omitted).

The structure of the statutory scheme here shows that a seller of an applicant's products falls outside the zone of interests protected by the Act—or, in other words, that FDA's denial of a manufacturer's application for marketing authorization does not "adversely affect" such a seller within the meaning of the Act. The Act provides that, when FDA denies an application, it must serve its order "to the applicant." 21 U.S.C. 387j(e). The Act does not require the agency to notify sellers or other members of the public of its decision. Just the opposite: "the intent to market a [new] tobacco product" is "often considered confidential commercial information," 86 Fed. Reg. 55,300, 55,398 (Oct. 5, 2021), and the Act requires FDA to protect the confidentiality of such information unless the manufacturer has publicly revealed its intent to market the product, see 21 U.S.C. 387f(c).

Even when the fact of an application or marketing denial order is made public, the Act may preclude FDA from disclosing the contents of the application, order, and administrative record to sellers and other members of the public. The Act provides that the "information reported to or otherwise obtained by" FDA as part of the application process "shall not be disclosed," except in limited circumstances. 21 U.S.C. 387f(c). Indeed, Reynolds has successfully moved to seal its filings in the court of appeals in order to protect "confidential and proprietary information concerning Vuse products' design, components, construction, specifications, chemical makeup, ingredients, and other highly sensitive technical details that have not been made available to the public." *Vibe* C.A. Doc. 10, at 8 (Jan. 25, 2023). Reynolds observed that "FDA has repeatedly recognized the need to prevent public disclosure of confidential and

sensitive information contained in submissions like the Vuse applications." *Ibid.*

Those aspects of the statutory structure demonstrate that the denial of a manufacturer's application does not adversely affect a seller of its products within the meaning of the Act. It is implausible that Congress simultaneously granted sellers, whose interests are entirely derivative of those of the applicant, the right to challenge denial orders—yet denied the sellers notice of the orders and access to the information underlying the orders.

In addition, the Act forbids the sale of new tobacco products unless and until FDA authorizes it. See 21 U.S.C. 387j(a)(2)(A). The harm that Avail and the Convenience Stores Association assert here—lost sales of products that the Act prohibited them from selling in the first place—does not qualify as an "adverse effect" in the sense meant by Congress.

In ruling otherwise, the Fifth Circuit emphasized that an FDA marketing denial order "affect[s]" a seller by reducing its sales. App., *infra*, 4a. As explained above, however, the phrase "adversely affected" is a term of art in administrative law. See p. 9, *supra*. The critical question is not whether a denial order harms the seller in some way; it is whether that harm "constitutes adverse effect" within the meaning of the Act. *Newport News*, 514 U.S. at 126 (emphasis omitted). For the reasons given above, the Act's structure shows that it does not.

The Fifth Circuit also contrasted the judicial-review provision at issue here with a separate provision that permits only the "holder of an application" to challenge FDA's withdrawal of marking authorization that was previously granted. 21 U.S.C. 387j(d)(2); see App., *in-*

fra, 4a. But the court read too much into that difference in wording. The provision for judicial review that respondents invoked here authorizes judicial review not only of a "denial" of an application, but also of a "regulation" establishing, amending, or revoking a tobacco product standard. 21 U.S.C. 387*l*(a)(1). The phrase "holder of an application," used in the narrower provision specifically addressing judicial review only of withdrawal orders, would have been a poor fit for the full range of agency actions covered by the provision here.

If anything, the provision concerning review of withdrawal orders cuts against the Fifth Circuit's reading. As Judge Higginson explained, withdrawal orders, which require retailers to stop previously lawful sales, affect retailers' interests far more directly than denial orders. See App., *infra*, 7a (Higginson, J., dissenting). The Fifth Circuit did not explain why Congress would have wanted to allow retailers to challenge the denial of authorization to market a new tobacco product at the outset, but to allow only the applicant to challenge the withdrawal of marketing authorization that was previously granted.

2. The Fifth Circuit further erred by holding that Reynolds may file a petition for review in that circuit because "two [other] Petitioners," Avail and the Convenience Stores Association, are based in the Fifth Circuit. See App., *infra*, 3a; see *R.J. Reynolds Vapor Co.* v. *FDA*, 65 F.4th 182, 188 (5th Cir. 2023) ("[V]enue is proper in this circuit because *a* petitioner has its 'principal place of business' here.") (emphasis added). Venue under the Act is party-specific; a petitioner as to whom venue is improper may not tag along with a different petitioner as to whom it is proper.

The Act provides that a "person" may seek judicial review in the D.C. Circuit or the circuit where "*such person*" resides or has its principal place of business. 21 U.S.C. 387*l*(a)(1) (emphasis added). That statutory text plainly directs that a person's right to seek review in a circuit depends on *that person's* residence or principal place of business. Nothing in the text suggests that one person may file a petition for review in a circuit (other than the D.C. Circuit) where it neither resides nor has its principal place of business, so long as its petition is joined by a different person that is based there.

Precedent confirms that reading. "Faced with multi-party cases, [this] Court long ago held that venue must be proper as to each party." 14D Charles Alan Wright et al., *Federal Practice and Procedure* § 3807 (4th ed. 2023). Interpreting a provision authorizing venue in the district where "the plaintiff" resided, the Court found venue improper as to a co-plaintiff from a different district. *Smith* v. *Lyon*, 133 U.S. 315, 317 (1890); see *id.* at 317-320. Similarly, interpreting a provision authorizing venue in the district where "the defendant" resided, the Court found venue improper as to a co-defendant from a different district. *Camp* v. *Gress*, 250 U.S. 308, 311 (1919); see *id.* at 311-316. Of course, Congress could adopt a different approach in a particular venue statute, say by authorizing venue in a district where "*any* defendant resides." 28 U.S.C. 1391(g) (emphasis added). But nothing in the text or context of the special judicial-review provision in the Tobacco Control Act suggests that Congress departed from the traditional rule that "each plaintiff must be competent to sue" and "each defendant must be liable to be sued" in the chosen venue. *Smith*, 133 U.S. at 319 (citation omitted).

The Fifth Circuit's contrary rulings conflict with the Tenth Circuit's decision in *Amerada Petroleum Corp.* v. *Federal Power Commission*, 338 F.2d 808 (1964). That case arose under the Natural Gas Act, 15 U.S.C. 717 *et seq.*, which authorizes a natural-gas company to file a petition for review "in the court of appeals of the United States for any circuit wherein the natural-gas company to which the order relates is located or has its principal place of business, or in the United States Court of Appeals for the District of Columbia." 15 U.S.C. 717r(b). The Tenth Circuit read that provision to mean that out-of-circuit companies could not join a local company to seek review in that circuit. See *Amerada Petroleum*, 338 F.2d at 809-810. Yet the Fifth Circuit has approved exactly that maneuver under the materially similar venue provision here.

3. The Fifth Circuit's decisions additionally contradict elementary principles of statutory interpretation. This Court ordinarily reads statutes "so that effect is given to all provisions, so that no part will be inoperative or superfluous, void or insignificant." *Ysleta del Sur Pueblo* v. *Texas*, 596 U.S. 685, 698-699 (2022) (citation omitted). The Court also ordinarily avoids readings that facilitate ready "evasion of the law," *County of Maui* v. *Hawaii Wildlife Fund*, 140 S. Ct. 1462, 1473 (2020) (citation omitted), or that enable parties to "elude its provisions in the most easy manner," *The Emily*, 9 Wheat. 381, 389 (1824). And the Court has rejected readings of venue statutes that would "encourage gamesmanship" or "'create or multiply opportunities for forum shopping.'" *Atlantic Marine Construction Co.* v. *United States District Court*, 571 U.S. 49, 65 (2013) (citation omitted).

Contrary to those principles, the Fifth Circuit's interpretation nullifies the Act's venue restrictions, facilitates their ready circumvention, and encourages forum shopping. The Act provides that a person may file a petition for review in the circuit where it "resides" or has its "principal place of business." 21 U.S.C. 387*l*(a)(1). Yet under the decision below, an applicant may file a petition for review in a circuit where it neither resides nor maintains its principal place of business so long as it recruits a local gas station or convenience store to join its petition. The Act also designates the D.C. Circuit as the one circuit where any applicant may seek judicial review regardless of the applicant's location. See *ibid.* Yet under the decision below, an applicant may also seek judicial review in the Fifth Circuit through the simple expedient of finding a local retailer to join it.

B. The Question Presented Warrants This Court's Review

1. The Fifth Circuit initially answered the question presented here in its *Vibe* stay order. But the court did not just hold that venue was *likely* proper in the course of analyzing likelihood of success on the merits; rather, it held, in a published opinion, that "venue *is* proper in this circuit." *Reynolds*, 65 F.4th at 188 (emphasis added). The government filed a petition for rehearing en banc, but the Fifth Circuit denied that petition. See p. 6, *supra*.

The Fifth Circuit's later decisions confirm that the court regards the venue issue as settled. The government moved to transfer the petitions for review in *Vibe* and *Solo*, but the Fifth Circuit denied those motions. See p. 6, *supra*. The government also moved to dismiss or transfer in *Alto*, but the Fifth Circuit denied that motion as well. App., *infra*, 2a-5a. The court stated that "[s]tare decisis governs venue" and that it remained

"bound by [its] holding in the published opinion that venue is proper." *Id.* at 4a. Thus, unless this Court grants review and reverses, out-of-circuit manufacturers will be able to seek review in the Fifth Circuit and to circumvent unfavorable precedent in the D.C. Circuit and their own circuits.

2. The effects of the Fifth Circuit's interpretation of the Act extend beyond this case. Reynolds alone has filed three petitions for review in the Fifth Circuit. See p. 4, *supra*. On each occasion, Reynolds raised claims that would have been foreclosed, at least in part, by precedent in the D.C. Circuit and the Fourth Circuit, the two circuits in which judicial review of the denials of its applications would have been available under the Act. See *ibid.* Each time, Reynolds circumvented that adverse precedent by enlisting local retailers—a Texas convenience store and a Mississippi trade association—to join its petition. See p. 5, *supra*. And each time, the Fifth Circuit rejected the government's venue objection and stayed FDA's denial order. See pp. 5-7, *supra*.

Other out-of-circuit manufacturers have begun using the same tactic to obtain judicial review of FDA orders in the Fifth Circuit. For example, Fontem US, LLC, a manufacturer based in North Carolina, has filed a petition for review joined by a company that operates convenience stores in Mississippi and Louisiana—and has obtained a temporary stay from the Fifth Circuit. See Pet. for Review at 1-3, *Corr-Williams Co.* v. *FDA*, No. 24-60068 (Feb. 8, 2024); C.A. Doc. 82-2, at 1-2, *Corr-Williams*, *supra* (No. 24-60068) (Mar. 7, 2024). Shenzhen Youme Information Technology Co., a manufacturer based in Shenzhen, China, has filed a petition joined by a Texas retailer. See Pet. for Review at 1-3, *Shenzhen Youme Information Technology Co.* v. *FDA*,

No. 24-60060 (5th Cir. Feb. 5, 2024). And Shenzhen IVPS Technology Co., a different manufacturer based in Shenzhen, China, has filed a petition joined by a Texas distributor. See Pet. for Review at 1-3, *Shenzhen IVPS Technology Co.* v. *FDA*, No. 24-60032 (5th Cir. Jan. 19, 2024).

3. This Court should grant review to put a stop to that practice. The Court's functions include "supervising the administration of the judicial system." *Hollingsworth* v. *Perry*, 558 U.S. 183, 196 (2010) (per curiam). Fulfilling that role, the Court recently granted certiorari to correct a venue ruling that had led to rampant forum-shopping in patent cases. See *TC Heartland LLC* v. *Kraft Foods Group Brands LLC*, 581 U.S. 258, 263 (2017). The Court should grant review here for similar reasons.

Although the Fifth Circuit's decision does not create a circuit conflict specifically about the meaning of the Tobacco Control Act's venue provision, it does conflict with the Tenth Circuit's decision in *Amerada Petroleum* interpreting a materially similar venue provision. See p. 14, *supra*. In addition, the Fifth Circuit's interpretation of the Act undermines the authority of other courts of appeals in a manner that warrants this Court's intervention. The Fifth Circuit has repeatedly encroached on the domains of other circuits by hearing (and granting stays in) cases under the Tobacco Control Act that belong elsewhere. And the Fifth Circuit has repeatedly undermined the precedents of other circuits by enabling out-of-circuit manufacturers to evade those precedents. Because manufacturers across the country can now file petitions for review in the Fifth Circuit, moreover, it is unlikely that the question presented will

percolate in other courts of appeals or that a circuit conflict about that question will ever develop.

The Fifth Circuit's decisions also have had serious consequences for public health. As discussed above, the Fifth Circuit has repeatedly stayed FDA denial orders at the behest of out-of-circuit manufacturers. See pp. 4-7, 16, *supra*. Relying on those stays, manufacturers and sellers have continued selling e-cigarette products that FDA has never authorized. Those sales—which have occurred throughout the Nation, not just in the Fifth Circuit—contribute to a "youth vaping epidemic." *Avail Vapor, LLC* v. *FDA*, 55 F.4th 409, 426 (4th Cir. 2022), cert. denied, 144 S. Ct. 277 (2023). One study estimated that, in 2023, 420,000 middle- and high-school students used Reynolds' Vuse e-cigarette products. See Jan Birdsey et al., CDC, U.S. Dep't of Health and Human Services, *Tobacco Product Use Among U.S. Middle and High School Students—National Youth Tobacco Survey, 2023*, 72 Morbidity and Mortality Weekly Report 1180 (Nov. 3, 2023). According to estimates in the same study, 230,000 students used Shenzhen IVPS's "SMOK" brand e-cigarettes, 120,000 students used Fontem's "blu" brand e-cigarettes, and 70,000 students used Shenzhen Youme's "Suorin" brand e-cigarettes. *Ibid.* Those substantial practical consequences underscore the need for this Court's review.

The underlying merits issues in this case, which concern FDA's consideration of flavored e-cigarette products, overlap with the issues raised by FDA's pending petition for a writ of certiorari in *FDA* v. *Wages & White Lion Investments, L.L.C.*, No. 23-1038 (filed Mar. 19, 2024). But the threshold venue issue will remain important no matter how this Court resolves *Wages*. The judicial-review provision involved here applies to any

order denying authorization to market any new tobacco product. And out-of-circuit manufacturers have begun filing petitions for review in the Fifth Circuit even in cases that raise legal issues on the merits that are distinct from the one in *Wages*. See Pet. for Review, Ex. A at 6, *Shenzhen Youme*, *supra* (No. 24-60060) (denial of authorization to market an e-cigarette device that can be filled with liquids of the user's choice); Pet. for Review, Ex. A at 9-13, *Shenzhen IVPS*, *supra* (No. 24-60032) (same).

4. This Court should grant review even though the Fifth Circuit's order denying the motion to dismiss or transfer in *Alto* is interlocutory. It is well settled that "interlocutory orders of federal courts of appeals are reviewable on certiorari." Stephen M. Shapiro et al., *Supreme Court Practice* § 17.7, at 17-17 (2019); see *id.* § 4.18, at 4-54 to 4-55 (collecting cases). In particular, a party may seek certiorari from a court of appeals' order denying a motion to dismiss a petition for review. See *National Ass'n of Manufacturers* v. *Department of Defense*, 583 U.S. 109, 120 (2018).

To be sure, this Court generally denies petitions at an interlocutory stage of a case because litigants remain free to seek relief after final judgment. See, *e.g.*, *City of Ocala* v. *Rojas*, 143 S. Ct. 764, 765 (2023) (statement of Gorsuch, J., respecting the denial of certiorari). But that practice is not categorical. In particular, the Court has on many occasions granted petitions raising venue issues at an interlocutory stage of a case. See, *e.g.*, *TC Heartland*, 581 U.S. at 263; *Walden* v. *Fore*, 571 U.S. 277, 282 & n.5 (2014); *Atlantic Marine*, 571 U.S. at 54-55. *Alto* remains pending in the court of appeals following the denial of the government's motion to dismiss or transfer, and thus no final judgment on the merits has

been entered there. But as noted above, the Court granted certiorari in *National Association of Manufacturers* in a similar posture.

In addition, in *Mercantile National Bank* v. *Langdeau*, 371 U.S. 555 (1963), the Court held that a state supreme court's denial of a motion to transfer a case from one state court to another, as assertedly required by a federal statute governing suits against national banks, constituted a "final" judgment for purposes of the Court's jurisdiction under 28 U.S.C. 1257. See 371 U.S. at 557-558. Here, as there, postponing review of the question presented would serve no useful purpose. Because venue "is a separate and independent matter, anterior to the merits," *id.* at 558, further proceedings on the merits in the Fifth Circuit would not affect the resolution of the venue issue presented by this certiorari petition.

Postponing review would, rather, needlessly prolong the harms caused by the Fifth Circuit's interpretation of the Act. The Fifth Circuit has, over the government's objection, stayed proceedings in *Vibe*, *Solo*, and *Alto* pending the disposition of the government's petition for a writ of certiorari in *Wages*. See *Vibe* C.A. Doc. 314-2, at 1-3 (Feb. 15, 2024). Awaiting final judgment in these cases could thus involve a years-long delay. In the meantime, the Fifth Circuit's stays of FDA's denial orders would remain in effect, and Reynolds and other manufacturers would continue to sell e-cigarette products that FDA has never authorized.

Further, petitions for review filed by out-of-circuit manufacturers would continue to pile up in the Fifth Circuit. Granting review now would ensure that those petitions are considered in the first instance in the venues required by the Act. It would also avoid the dupli-

cation of effort and waste of resources that would occur if the Fifth Circuit were to consider all those cases on the merits, only for this Court to hold later that venue was improper all along and that the Fifth Circuit should have transferred the petitions to other courts. Cf. *Langdeau*, 371 U.S. at 558 ("[I]t serves the policy underlying the requirement of finality * * * to determine now in which state court appellants may be tried, rather than to subject them * * * to long and complex litigation which may be all for naught if consideration of the preliminary question of venue is postponed until the conclusion of the proceedings.").

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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MAY 2024

APPENDIX

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 23-60037

R.J. REYNOLDS VAPOR COMPANY; RJR VAPOR COMPANY, L.L.C.; AVAIL VAPOR TEXAS, L.L.C.; MISSISSIPPI PETROLEUM MARKETERS AND CONVENIENCE STORES ASSOCIATION, PETITIONERS

v.

FOOD & DRUG ADMINISTRATION; ROBERT CALIFF, IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF THE UNITED STATES FOOD & DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, RESPONDENTS

CONSOLIDATED WITH

No. 23-60128

R.J. REYNOLDS VAPOR COMPANY; RJR VAPOR COMPANY, L.L.C.; AVAIL VAPOR TEXAS, L.L.C.; MISSISSIPPI PETROLEUM MARKETERS AND CONVENIENCE STORES ASSOCIATION, PETITIONERS

v.

UNITED STATES FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF, COMMISSIONER OF FOOD AND DRUGS; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, RESPONDENTS

CONSOLIDATED WITH

No. 23-60545

R.J. REYNOLDS VAPOR COMPANY; RJR VAPOR COMPANY, L.L.C.; MISSISSIPPI PETROLEUM MARKETERS AND CONVENIENCE STORES ASSOCIATION; AVAIL VAPOR TEXAS, L.L.C., PETITIONERS

v.

FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF, COMMISSIONER OF FOOD AND DRUGS; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, RESPONDENTS

Filed: Feb. 2, 2024

Petition for Review from an Order of the Food & Drug Administration
Agency No. PM0000973
Agency No. PM0000637
Agency No. PM0000713

UNPUBLISHED ORDER

Before JONES, HIGGINSON, and HO, *Circuit Judges*.

PER CURIAM:

In its latest Motion to Dismiss or Transfer, the Food and Drug Administration ("FDA") argues that Petitioners R.J. Reynolds Vapor Co. et al. do not meet the requirements of the Family Smoking Prevention and Tobacco Control Act for filing their petition here in the Fifth Circuit. This Act provides that "any person ad-

versely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business." 21 U.S.C. § 387*l*(a)(1). We DENY the Motion. All the Petitioners are "person[s] adversely affected" under the Act, and two of the Petitioners, Avail Vapor Texas and the Mississippi Petroleum Marketers and Convenience Stores Association, have their principal places of business here in the Fifth Circuit.

I.

This Motion is the latest stage in an ongoing saga between the R.J. Reynolds's vape devices manufacturing and the FDA. The FDA has denied R.J. Reynolds's applications to market various e-cigarettes. *See* 21 U.S.C. § 387j(a)(1)-(2). At issue in this case, No. 23-60545, are menthol- and berry-flavored "Alto" e-cigarettes. Only the menthol flavor is currently on the market. Previous stay orders in the lead case, No. 23-60037, have concerned menthol-flavored "Vibe" and "Solo" e-cigarettes. This case was consolidated with No. 23-60037 in an unpublished order on October 19, 2023. In this Motion, the FDA renews arguments it raised in its previous motion to transfer, which this court denied in a one-sentence, unpublished per curiam opinion on June 27, 2023. This court has also already held that venue is proper. *R.J. Reynolds Vapor Co. v.* FDA, 65 F.4th 182, 188 (5th Cir. 2023).

II.

This court remains bound by our holding in the published opinion that venue is proper in this circuit. *R.J. Reynolds Vapor Co*, 65 F.4th at 188. The only differences between that earlier case and this one is that another R.J. Reynolds product was involved, and at least one different distributor. The FDA did not make its present statutory arguments at that time. Stare decisis governs venue here so long as the distributors have standing, which they do.

The FDA's arguments to the contrary are unavailing. Its arguments that the retail Petitioners could not lawfully have been selling the e-cigarettes without prior approval does not show that the Petitioners lose standing. The Tobacco Control Act gives standing to "*any* person adversely affected." 21 U.S.C. § 387*l*(a)(1) (emphasis added). Retail Petitioner Avail Vapor Texas submitted a declaration that "[i]f Avail were not allowed to sell Vuse products, Vuse Inspiration Store would have to close, and Avail would cease its business operations." The Tobacco Control Act grants the Petitioners statutory standing to challenge FDA decisions that affect them.

Similarly, the FDA's argument that the Act states elsewhere that only the "holder of [the] application" can challenge a marketing *withdrawal* order, 21 U.S.C. § 387j(d)(2), has no bearing on who can challenge a *denial* order. "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23, 104 S. Ct. 296 (1983). Here, Congress

did not limit access to the courts for those challenging a *denial* order in the same way it did for those challenging a *withdrawal* order. If the FDA disagrees with Congress's policy choice in so drafting the Tobacco Control Act, its concerns are better directed to Congress than to this court. *See Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 462, 122 S. Ct. 941 (2002) ("We will not alter the text in order to satisfy the policy preferences of the Commissioner. These are battles that should be fought among the political branches and the industry.").

The FDA's accusation of forum shopping fails because the retail entities are undisputedly in this circuit, and they provided declarations that they would "cease business operations" if the FDA's denial order went into effect. Its arguments relating to the confidentiality provisions are not probative of the meaning of the phrase "adversely affected" in a different portion of the Act. And its argument that the Tobacco Control Act should be read to favor the protection of the public from tobacco over the interests of the retail Petitioners fails in light of the statutory purpose of "continu[ing] to permit the sale of tobacco products to adults." *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776, 1782.

III.

All the Petitioners have statutory standing as "person[s] adversely affected" under the Tobacco Control Act, and both Avail Vapor Texas and the Mississippi Petroleum Marketers and Convenience Stores Association have their principal place of business in the Fifth Circuit. We therefore DENY the FDA's Motion to Transfer or Dismiss.

STEPHEN A. HIGGINSON, *Circuit Judge*:

In the above-captioned consolidated cases before us —Case Nos. 23-60037, 23-60128, and 23-60545—are three pending motions: (1) R.J. Reynolds Vapor Company's (Reynolds) motion for stay pending review in Case No. 23-60545 (concerning Reynolds's premarket application for its "Alto" product); (2) the FDA's motion to dismiss or transfer Case No. 23-60545; and (3) the FDA's motion to lift the previously-granted stays of proceedings in Case Nos. 23-60037 and 23-60128 (concerning Reynolds's premarket application for its "Vibe" and "Solo" products, respectively).

A motions panel of this court previously accepted that venue was proper in Case Nos. 23-60037 and 23-60128 because "*a* petitioner"—Mississippi Petroleum Marketers and Convenience Stores Association—"has its 'principal place of business here'" in the Fifth Circuit, while "at least one" *other* petitioner, Reynolds, "has standing." *R.J. Reynolds Vapor Company v. FDA*, 65 F.4th 182, 188 (5th Cir. 2023) (emphasis added). In its pending motion to dismiss or transfer, the FDA contends this "mix-and-match approach" is impermissible because it violates the requirements set forth in 21 U.S.C. § 387l(a) and is at odds with the structure and purpose of the Tobacco Control Act (TCA).

While Petitioners are correct that the FDA has unsuccessfully raised these arguments regarding venue in prior related matters, the FDA is equally correct in underscoring that neither of the two prior motions panels addressed the government's arguments on the merits. And although today's panel does engage, it fails to address the principal defect with Petitioners' argument: its position would render the venue limitations in 21

U.S.C. § 387l(a)(1) surplusage. This expansive reading of venue cannot seem to be reconciled with the other provisions of the TCA—including retailers' inability to sue when marketing authorization is withdrawn, *see* 21 U.S.C. § 387j(d)(2), which naturally would more directly impair their interests; and the confidentiality requirements regarding the information contained in retailers' marketing applications, *see, e.g.*, 21 U.S.C. § 387f(c). Nor, ultimately, can Reynolds' position be harmonized with the purpose of the TCA, which the panel majority characterizes as "continu[ing] to permit the sale of tobacco products to adults," truncating the remainder of the text in that clause—"in conjunction with measures to ensure that they are not sold or accessible to underage purchasers"—as well as skipping over the nine other stated purposes, including "to ensure that the [FDA] has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco" and "to authorize the [FDA] to set national standards controlling the manufacture of tobacco products." Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776, 1781-82.

A fair reading of the text and the purpose of the TCA compels me to dissent. I would transfer this case to either the D.C. Circuit or the Fourth Circuit. Those two courts have already ruled on questions central to these cases in a manner that is adverse to Reynolds' position. *See Prohibition Juice Co. v. FDA*, 45 F.4th 8 (D.C. Cir. 2022); *Avail Vapor, LLC v. FDA*, 55 F.4th 409 (4th Cir. 2022), *cert. denied*, No. 22-1112, 2023 WL 6558399 (Oct. 10, 2023). By contrast, our court had as well, but vacated and effectively reversed that decision *en banc*, in conflict with the majority of circuits to have addressed

the same issue. *See Wages & White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357, 392 (5th Cir. 2024) (Haynes, J., dissenting).

APPENDIX B

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Oct. 12, 2023

DENIAL

R.J. Reynolds Vapor Company
Attention: Ryan Potts, Ph.D.
Senior Vice President, Scientific & Regulatory Affairs
RAI Services Company
950 Reynolds Boulevard
Winston-Salem, NC 27101

FDA Submission Tracking Numbers (STNs): Multiple STNs, see Appendix A

Dear Ryan Potts:

We are denying a marketing granted order for the products identified in Appendix A. Refer to Appendix B for a list of amendments received in support of your applications.

The statute places the burden on the applicant to make the required showing by providing that FDA "shall deny an application" for a product to receive a PMTA marketing authorization if, "upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product," FDA finds that "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the

public health" (APPH). Based on our review of your PMTAs[1],we determined that the new products, as described in your applications and specified in Appendix A, lack sufficient evidence to demonstrate that the marketing of these products is APPH. You cannot introduce or deliver for introduction these products into interstate commerce in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA.

If you choose to submit new applications for these products, you must fulfill all requirements set forth in section 910(b)(1) and 21 CFR Part 1114. You may provide information to fulfill some of these requirements by including an authorization for FDA to cross-reference a Tobacco Product Master File.[2] You may not cross-reference information submitted in the PMTAs subject to this Denial.

Based on review of your PMTAs, we identified the following key basis for our determination:

1. Your PMTAs (PM0000973.PD4, PM0000973.PD5, PM0000973.PD8, PM0000973.PD9, PM0000973.PD12, and PM0000973.PD13) lack sufficient evidence demonstrating that the new products have a potential to benefit adult smokers in terms of complete switching or significant cigarette use reduction that would outweigh the risk to youth.

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[1] Premarket Tobacco Product Applications (PMTAs) submitted under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

[2] See guidelines at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files

There is substantial evidence that flavored ENDS (including menthol), like the new products, have significant appeal to youth and are associated with youth initiation of such products. The marketing restrictions and other mitigation measures that you proposed cannot mitigate these risks to youth sufficiently to reduce the magnitude of adult benefit required to demonstrate that permitting the marketing of these products would be APPH. In light of the known risks to youth of marketing flavored ENDS (including menthol flavor), robust and reliable evidence is needed regarding the magnitude of the potential benefit to adult smokers. This evidence could have been provided using a randomized controlled trial, longitudinal cohort study, or other reliable and robust evidence demonstrating the benefit of the new product to adult smokers relative to tobacco-flavored ENDS products, which present less risk to youth. Such evidence should have included an appropriate comparator tobacco-flavored ENDS. Reliable and robust evidence is needed to evaluate the impact of the new product as compared to tobacco-flavored products on adult combusted cigarette users' complete switching or significant reduction in cigarette use over time because tobacco-flavored products have not been shown to present the same risks to youth as tobacco products with other characterizing flavors. Whether other products give adult combusted cigarette users comparable options for complete switching or significant cigarette reduction bears on the extent of the public health benefit that the new product arguably provides to that population. Moreover, although this evidence is necessary to demonstrate that the subject ENDS

provide benefits for adult combusted cigarette users, it may not be sufficient to demonstrate that permitting the marketing of the subject ENDS is appropriate for the protection of the public health. Applications containing this evidence of benefit to adults would still be evaluated to determine that the totality of the evidence supports a marketing authorization.

Based on the information that you provided, there is a lack of evidence to demonstrate that the subject ENDS, relative to tobacco-flavored ENDS, would provide an added benefit for adult smokers that is adequate to outweigh the substantial risks to youth. Your PMTAs included information from longitudinal studies, the PATH Study and the Colorado Longitudinal Study, which assessed changes in tobacco use behavior—namely, the extent to which adult smokers become dual users or exclusive ENDS users through the use of ENDS products. These results showed that a small percentage of smokers (~5%) completely switch to ENDS. Between Wave 1 and Wave 3 of the PATH Study, 1.5% of adults who were exclusively smoking at Wave 1 transitioned to exclusive ENDS use. An additional 5.3% of adult dual users of cigarettes and ENDS at baseline became exclusive ENDS users. In the Colorado Longitudinal Study, 4.6% of baseline dual users had completely switched to ENDS at the 6-month follow-up. However, these studies were not brand, product, or flavor-specific, and the application provided no information to demonstrate that these conclusions apply to the subject products, much less that your flavored new products are more likely to promote complete switching or significant cigarette reduction compared to tobacco-flavored products. Further, your PMTAs included

data from the National Tobacco Behavior Monitor (NTBM) and Total Tobacco Migration Tracker (TTM) population surveys, which showed Vuse Solo (as a proxy for Vuse Alto) users who reported using a non-tobacco flavor had a significantly higher odds of being a former vs. current cigarette smoker (NTBM: OR = 1.97, 95% CI: 1.40-2.77, $p<0.0001$; TTM: OR = 2.16, 95% CI: 1.21-3.86, $p<0.009$). These data are from users of Vuse Solo and therefore are not specific to the new products. Moreover, these analyses were cross-sectional and thus do not enable a reliable evaluation of former smokers' behavior change over time. In addition, the published literature on the role of flavored ENDS and smoking cessation or reduction did not demonstrate that flavored ENDS are more effective in promoting complete switching or significant cigarette reduction relative to tobacco-flavored ENDS.

Thus, based on your studies and the peer-reviewed studies in the literature, FDA is unable to determine whether or to what extent your flavored new products facilitate complete switching or significant cigarette reduction as compared to tobacco-flavored ENDS products. Given the known risks to youth of marketing flavored ENDS, FDA needed this information to demonstrate that your flavored new products (PM0000973.PD4, PM0000973.PD5, PM0000973.PD8, PM0000973.PD9, PM0000973.PD12, PM0000973.PD13) would provide a benefit to adult smokers sufficient to outweigh their risk to youth.

The PMTAs did not contain evidence (whether from an RCT, longitudinal cohort, or other study design) regarding the impact of the new products on com-

> plete switching or significantly reducing cigarette use that could adequately demonstrate that the flavored new products were more likely to promote complete switching or significant cigarette reduction compared to tobacco-flavored products that present less risk of youth initiation and use. The other evidence provided in the PMTAs regarding the potential benefit to adult users is likewise inadequate to make the required showing, due to the absence of robust, product-specific evidence of actual behavior change, in the form of complete switching or significant reduction in CPD among adult CC smokers, beyond that of tobacco-flavored ENDS products. Together, based on the information provided in the PMTAs and the available evidence, the PMTAs lack sufficient evidence to show that the new products have the potential to benefit adult smokers that wouldoutweigh the risk to youth.

The review concluded that key evidence demonstrating APPH is absent. Therefore, scientific review did not proceed to assess other aspects of the applications. FDA finds that it is not practicable to identify at this time an exhaustive list of all possible deficiencies.

Your PMTAs lack sufficient information to support a finding of APPH. Because you have not met your burden of "showing" that permitting the marketing of the new products would be APPH as required by Section 910(c)(2)(A), we are issuing a marketing denial order. Your products are misbranded under section 903(a)(6) of the FD&C Act and adulterated under section 902(6)(A) of the FD&C Act. Failure to comply with the FD&C Act may result in FDA regulatory action without further notice. These actions may include, but are not

limited to, civil money penalties, seizure, and/or injunction.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[3],[4] using eSubmitter.[5] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[6]; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, please contact Sequoia Bacon, M.H.A., Regulatory Health Project Manager, at (301) 796-0736 or Sequoia.Bacon@fda.hhs.gov.

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[3] For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal

[4] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

[5] For more information about eSubmitter, see https://www.fda.gov/industry/fda-esubmitter

[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

Sincerely,

Digitally signed by Benjamin Apelberg -S
Date: 2023.10.12 07:00:35 -04'00'

Benjamin Apelberg, Ph.D. Deputy Director
Office of Science
Center for Tobacco Products

Enclosures: **(if provided electronically, the Appendix is not included in physical mail):**

Appendix A—New Tobacco Products Subject of This Letter

Appendix B—Amendments and Additional Submissions Received for This Applicant

Appendix A[7,8,9]

New Tobacco Products Subject of This Letter

Common Attributes of PMTAs	
Submission Date	September 4, 2020
Receipt Date	September 4, 2020
Applicant	R.J. Reynolds Vapor Company
Product Manufacturer	R.J. Reynolds Vapor Company
Product Category	ENDS (VAPES)
Product Subcategory	Closed E-Liquid
Attributes	**New Tobacco Product**
STN	PM0000973
Static Product ID	PD4
Product Name	Vuse Alto Pod Menthol 5%
Package Type	Cartridge
Package Quantity	1 Cartridge
Characterizing Flavor (CF)	Menthol

[7] Product name is the brand/sub-brand or other commercial name used in commercial distribution.

[8] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.

[9] We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.

Nicotine Source	Tobacco
Nicotine Concentration	57.8 mg/ml
PG/VG Ratio	44/56
E-Liquid Volume	1.8 ml
Additional Property	Nicotine Content: 5.0% w/w, Length: 46.1 mm, Diameter: 19.0 mm
STN	PM0000973
Static Product ID	PDS
Product Name	Vuse Alto Pod Mixed Berry 5%
Package Type	Cartridge
Package Quantity	1 Cartridge
CF	Flavored
Flavored CF, as identified	Mixed Berry
Nicotine Source	Tobacco
Nicotine Concentration	57.8 mg/ml
PG/VG Ratio	44/56
E-Liquid Volume	1.8 ml
Additional Property	Nicotine Content: 5.0% w/w, Length: 46.1 mm, Diameter: 19.0 mm

STN	PM0000973
Static Product ID	PD8
Product Name	Vuse Alto Pod Menthol 2.4%
Package Type	Cartridge
Package Quantity	1 Cartridge
CF	Menthol
Nicotine Concentration	27.4 mg/mL
PG/VG Ratio	47/53
E-Liquid Volume	1.8 mL
Additional Property	Nicotine Content: 2.4% w/w, Length: 46.1 mm, Diameter: 19.0 mm
STN	PM0000973
Static Product ID	PD9
Product Name	Vuse Alto Pod Mixed Berry 2.4%
Package Type	Cartridge
Package Quantity	1 Cartridge
CF	Flavored
Flavored CF, as identified	Mixed Bery
Nicotine Source	Tobacco
Nicotine Concentration	27.4 mg/mL

PG/VG Ratio	46/54
E-Liquid Volume	1.8 mL
Additional Property	Nicotine Content: 2/4% w/w, Length: 46.1 mm, Diameter: 19.0 mm
STN	PM0000973
Static Product ID	PD12
Product Name	Vuse Alto Pod Menthol 1.8%
Package Type	Cartridge
Package Quantity	1 Cartridge
CF	Menthol
Nicotine Source	Tobacco
Nicotine Concentration	20.5 mg/mL
PG/VG Ratio	47/53
E-Liquid Volume	1.8 mL
Additional Property	Nicotine Content: 1.8% w/w, Length: 46.1 mm, Diameter: 19.0 mm
STN	PM0000973
Static Product ID	PD13
Product Name	Vuse Alto Pod Mixed Berry 1.8%
Package Type	Cartridge

Package Quantity	1 Cartridge
CF	Flavored
Flavored CF, as identified	Mixed Berry
Nicotine Source	Tobacco
Nicotine Concentration	20.5 mg/mL
PG/VG Ratio	47/53
E-Liquid Volume	1.8 mL
Additional Property	Nicotine Content: 1.8% w/w, Length: 46.1 mm, Diamenter: 19.0 mm

Appendix B

Amendments Received for These Applications

Submission Date	Receipt Date	Applications being amended	Reviewed	Brief Description
April 17, 2021	April 17, 201	All	Yes	Correction or clarification to original submission
August 24, 2021	August 24, 2021	All	Yes	Correction or clarification to original submission
September 21, 2021	September 21, 2021	All	No, Amendment withdrawn	Request to add four additional PMTAs. (This results in a new PMTA, not an amendment.)
June 20, 2022	June 20, 2022	All	Yes	Correction or clarification to original submission
June 30, 2022	June 30, 2022	All	Yes	Response to inspection request letter
July 13, 2022	July 13, 2022	All	Yes	Notification of additional manufacturing site

September 2, 2022	September 2, 2022	All	Yes	Notification of additional manufacturing site
September 14, 2022	September 14, 2022	All	Yes	Response to request for information
October 3, 2022	October 3, 2022	All	Yes	Response to request for information
January 13, 2023	January 13, 2023	All	Yes	Notification of additional manufacturing site

APPENDIX C

21 U.S.C. 387*l*(a)(1) provides:

Judicial review

(a) Right to review

(1) In general

Not later than 30 days after—

(A) the promulgation of a regulation under section 387g of this title establishing, amending, or revoking a tobacco product standard; or

(B) a denial of an application under section 387j(c) of this title,

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.