FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

DRIP MORE LLC, *Petitioner*, v. U.S. FOOD & DRUG ADMINISTRATION, *Respondent*.	No.21-71380 OPINION

On Petition for Review of an Order of the
Food & Drug Administration

Argued and Submitted June 11, 2026
San Francisco, California

Filed August 10, 2026

Before: Jacqueline H. Nguyen and Lawrence VanDyke, Circuit Judges, and Robert S. Huie,[*] District Judge.

Opinion by Judge Huie

[*] The Honorable Robert S. Huie, United States District Judge for the Southern District of California, sitting by designation.

SUMMARY[**]

Food & Drug Administration

The panel denied a petition for review of an order of the Food & Drug Administration ("FDA") denying Drip More LLC's premarket applications seeking FDA authorization to sell its candy- and fruit-flavored electronic nicotine delivery systems ("ENDS")—products popularly known as e-cigarettes or vapes.

The Family Smoking Prevention and Tobacco Control Act ("TCA") requires manufacturers to apply to the FDA for authorization prior to selling new tobacco products, and provides that the FDA "shall deny" such applications unless the manufacturer shows its product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). In denying Drip More's applications, the FDA cited Drip More's failure to provide evidence that robustly and reliably evaluated any beneficial impact, for adult smokers, of Drip More's flavored products compared to tobacco-flavored ENDS, in light of the known risks to youth of marketing flavored ENDS.

Drip More argued that the FDA acted arbitrarily and capriciously in denying the applications based on Drip More's failure to provide comparative efficacy evidence, resulting in the FDA effectively ignoring other relevant evidence in the applications. The panel held that (1) the FDA's denial of Drip More's premarket applications based on Drip More's failure to provide evidence of comparative

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

efficacy was not arbitrary and capricious where Drip More offered no evidence or explanation to distinguish the risk to youth posed by its flavored ENDS; and (2) the FDA explained its reasons for not addressing Drip More's marketing plan, and any error in declining to consider Drip More's plans for marketing and access restrictions was harmless. Finally, the panel rejected Drip More's argument that the FDA's denial order erroneously extended to fourteen of Drip More's products that have "zero nicotine" options—products that Drip More maintained were outside the scope of the TCA—because Drip More represented in its applications that its "zero nicotine" products were covered by the TCA.

Drip More next argued that the FDA's application of the comparative efficacy requirement to deny Drip More's premarket applications violated the TCA and the Administrative Procedure Act ("APA"), because the FDA was only able to impose such a requirement through notice-and-comment rulemaking. The panel held that the FDA was not required to engage in notice-and-comment rulemaking, under either the TCA or the APA, before applying a comparative efficacy requirement to deny Drip More's applications.

COUNSEL

Eric P. Gotting (argued), Keller and Heckman LLP, Washington, D.C., for Petitioner.

Benjamin Lewis (argued) and Joshua M. Koppel, Attorneys, Appellate Staff, Civil Division; Eric B. Beckenhauer, Deputy Assistant Attorney General; United States Department of Justice, Washington, D.C.; Maggie R. Redden, Associate Chief Counsel; Wendy S. Vicente, Deputy Chief Counsel, Litigation; Sean R. Keveney, Chief Counsel, Food and Drug Administration; Washington, D.C.; Michael B. Stuart, General Counsel, United States Department of Health and Human Services, Washington, D.C.; for Respondent.

OPINION

HUIE, District Judge:

The Family Smoking Prevention and Tobacco Control Act ("TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), requires manufacturers to apply to the Food and Drug Administration ("FDA") for authorization prior to selling new tobacco products, and provides that the FDA "shall deny" such applications unless the manufacturer shows its product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A).

Petitioner Drip More LLC submitted premarket applications seeking FDA authorization to sell its candy- and fruit-flavored electronic nicotine delivery systems

("ENDS")—products popularly known as e-cigarettes or vapes. The FDA issued a marketing denial order on Drip More's applications, citing Drip More's failure to provide evidence that robustly and reliably evaluated any beneficial impact, for adult smokers, of Drip More's flavored products compared to tobacco-flavored ENDS.

Drip More petitions for review of the denial order, contending that the FDA, in requiring such comparative efficacy evidence, acted arbitrarily and capriciously in violation of the TCA and the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. Drip More also contends that before applying a comparative efficacy standard here, the FDA was required by both the TCA and the APA to engage in notice-and-comment rulemaking.

This Court in *Lotus Vaping Technologies, LLC v. U.S. Food & Drug Administration*, 73 F.4th 657 (9th Cir. 2023), and the Supreme Court in *Food & Drug Administration v. Wages & White Lion Investments, LLC*, 604 U.S. 542, 578–79 (2025) ("*Wages*"), addressed arguments similar to those raised by Drip More here, that the FDA's comparative efficacy requirement was arbitrary and capricious. Following the textual analysis in those cases, we hold that the FDA's denial here was not arbitrary and capricious, and we further hold that the FDA was not required to engage in notice-and-comment rulemaking prior to applying a comparative efficacy requirement to Drip More's application.

I. BACKGROUND

A.

Congress enacted the TCA in 2009 to address what it found to be a pediatric public health crisis of "considerable

proportions." Pub. L. No. 111-31, § 2(1), 123 Stat. at 1777. Congress determined that virtually all new tobacco users initiate use before reaching the minimum legal purchase age, and that the overwhelming majority become addicted to nicotine before the age of eighteen. *Id*. § 2(4), 123 Stat. at 1777; § 2(31), 123 Stat. at 1779. Recognizing that prior regulatory efforts had failed and that tobacco companies had long regarded young people as a "crucial segment" of their market, Congress, through the TCA, vested the FDA with comprehensive authority to regulate the manufacturing, marketing, sale, and distribution of tobacco products, *id*. § 2(6), (24), 123 Stat. at 1777–78, as well as to "by regulation deem[]" new products subject to the Act, 21 U.S.C. § 387a; *see Wages*, 604 U.S. at 551.[1]

To pursue its dual aims of (1) minimizing tobacco use by young people and (2) promoting cessation of tobacco use among adult users, Pub. L. No. 111-31, §§ 3(2), (9), 123 Stat. at 1781–82, Congress required manufacturers to obtain the FDA's authorization before marketing new tobacco products, *see* 21 U.S.C. §§ 387j(a)(1)(A), (a)(2).[2] This process requires manufacturers to submit a premarket application that includes, among other information, full reports of all investigations made to show the health risks of the applicant's tobacco product, "and whether such tobacco product presents less risk than other tobacco products." *Id.*

[1] In *Wages*, an opinion analyzing a nearly contemporaneous FDA adjudication of premarket applications, the Supreme Court provided a comprehensive overview of the statutory and regulatory scheme governing the FDA's authority over tobacco regulation. *See* 604 U.S. at 548–61.

[2] "New tobacco products" are tobacco products that were not marketed in the United States prior to February 15, 2007. *See* § 387j(a)(1)(A), (a)(2).

§ 387j(b)(1)(A). For a new product to be approved, the applicant must demonstrate that marketing its product would be "appropriate for the protection of the public health" ("APPH")—or else the FDA "shall deny" the application. *Id.* § 387j(c)(2)(A).

When evaluating whether a product meets the APPH standard, "the FDA must consider the risks and benefits to the population as a whole and take into account the increased or decreased likelihood of two outcomes: first, that the new product will induce users of existing tobacco products such as conventional cigarettes to stop using those products and, second, that those who do not use tobacco products will start using them." *Wages*, 604 U.S. at 552 (simplified). The FDA's determination must rest on "well-controlled investigations" or other "valid scientific evidence" drawn from both the applicant's submission and "any other information" before the agency. 21 U.S.C. § 387j(c)(2), (5).

B.

ENDS were introduced to the U.S. market in 2007, and initially escaped the FDA's regulatory reach. *Wages*, 604 U.S. at 553, 555 (citing Dep't. of Health & Hum. Servs., *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* 9 (2016)). Unlike combustible cigarettes, ENDS use a battery-powered heating element to convert liquid nicotine into an aerosol that users inhale. *Id.* at 553. ENDS come in thousands of flavors; these include "not only flavors that [are] familiar to cigarette smokers (tobacco and menthol) but also fruit, candy, and dessert flavors that [are] appealing to non-smokers." *Id.* at 555.

ENDS quickly "became ubiquitous" and their sales "surged exponentially" after 2010, *id.* at 553 (simplified), resulting in "rampant and climbing" e-cigarette use among

middle and high school students, *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 275 (D.C. Cir. 2019). According to one estimate, in 2020 "approximately 3.6 million American middle- and high-school students used an e-cigarette within a 30-day period." *Wages*, 604 U.S. at 554–55 (citing Cong. Research Serv., H. Sheikh & V. Green, *FDA Regulation of Tobacco Products* 1 (2021)). Research led officials to conclude that a key driver of high youth demand for ENDS products is the "kaleidoscope of flavor options" that appeal to them, including fruit, candy, and dessert flavors. *Id.* at 555.

The surge in youth use of ENDS in part prompted the FDA to exercise its statutory authority to deem e-cigarettes subject to the TCA and its premarket authorization requirements. *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*, 81 Fed. Reg. 28,974, 28,984, 29,028–29 (May 10, 2016); 21 U.S.C. § 387a. The FDA's rulemaking reflected the "fierce public debate about the potential benefits and harms of e-cigarettes." *Wages*, 604 U.S. at 554. On one hand, ENDS products can "enable current smokers who are addicted to nicotine to reduce exposure to some of the more harmful byproducts of traditional combustible cigarettes." *Id.* On the other hand, they create their own health risks associated with the emission of "potentially toxic substances," including particulates, metals, and nicotine. *Id.* at 553–54 (simplified). Regarding risk to youth, the FDA recognized that inhaled nicotine from an ENDS product "may be as addictive as inhaled nicotine delivered by combusted tobacco products," and that "nicotine exposure during adolescence may have lasting adverse consequences for brain development." 81 Fed. Reg.

at 29,033. The rulemaking also reflected the "concern that the use of e-cigarettes by non-smokers—and especially young non-smokers—may eventually lead them to smoke conventional cigarettes," which carry even greater health risks. *Wages*, 604 U.S. at 554.

Following the deeming regulation, the majority of ENDS products were retroactively subject to the TCA's premarket authorization regime. *Id.* at 555; 21 U.S.C. § 387j(a)(1)(A).

C.

Drip More manufactures flavored e-liquids designed for use in ENDS. The company was established in 2016, "with the goal of helping adult smokers find an alternative to traditional cigarettes." Drip More offers a variety of e-liquid flavors under the brand name Candy King, with flavors such as "Berry Dweebz," "Ice Worms," "Peachy Rings," "Strawberry Bubblegum," and "Lemon Drops." Its products are subject to the TCA's premarket authorization requirement, and it submitted its applications for 64 products on September 9, 2020.

On October 14, 2021, the FDA issued a marketing denial order for Drip More's products. The FDA determined that Drip More had not met its burden of demonstrating that its products "would be appropriate for the protection of the public health." The "key basis" for its determination was that Drip More's applications "lack[ed] sufficient evidence demonstrating that [its] flavored ENDS will provide a benefit to adult users that would be adequate to outweigh the risks to youth." The denial order explained that, "[i]n light of the known risks to youth of marketing flavored ENDS, robust and reliable evidence is needed regarding the magnitude of the potential benefit to adult smokers." The FDA elaborated, "[t]his evidence could have been provided

using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of [Drip More's] flavored ENDS products over an appropriate comparator tobacco-flavored ENDS," or with other reliable and robust evidence evaluating "the impact of the new flavored vs. tobacco-flavored products on adult smokers' switching or cigarette reduction over time." In other words, because non-tobacco-flavored ENDS are more enticing to children than tobacco-flavored ENDS, the FDA required comparative evidence of the benefits—in terms of getting adult smokers to switch from combustible cigarettes—associated with Drip More's non-tobacco-flavored ENDS relative to tobacco-flavored ENDS. Because such "key evidence demonstrating APPH [was] absent" from the applications, the FDA's "scientific review did not proceed to assess other aspects of the applications."

The marketing denial order was accompanied by a Technical Project Lead ("TPL") Review that provided further context for the FDA's denial. This document explained, among other things, that the reason for the FDA's requirement of comparative efficacy evidence for Drip More's flavored ENDS products was to offset the increased risk to youth associated with such flavored offerings relative to tobacco-flavored ENDS.

The TPL Review began with a literature review supporting the FDA's "basis for requiring reliable, robust evidence to demonstrate benefit" to the population as a whole. The FDA reasoned that "[t]he published literature is sufficient to demonstrate the substantial appeal to youth of flavored ENDS, because it is robust and consistent," and "the preference for use of flavored ENDS among youth is consistently demonstrated across large, national surveys and

longitudinal cohort studies."[3] The agency stated that the scientific literature shows that "the availability of a broad range of flavors is one of the primary reasons for the popularity of ENDS among youth." The TPL Review discussed results from the FDA's National Youth Tobacco Survey ("NYTS"), including data showing that "the majority of youth who use ENDS report using a flavored ENDS product[,]" and their use of flavored ENDS products has increased over time.

The TPL Review stated that the youth appeal of flavored ENDS products was especially concerning because "youth are considered a vulnerable population," as their "brains are more vulnerable to nicotine's effects than the adult brain due to ongoing neural development." The FDA further found that flavors may "increase nicotine exposure by potentially influencing the rate of nicotine absorption." This vulnerability, and the potential effect of the appeal of flavoring, were reflected in "the data [that] also suggest [youth ENDS] use is leading to increases in nicotine dependence."

The FDA concluded that the combination of these observations—that youth users are more likely to use flavored ENDS than adult users, and that ENDS use is particularly harmful to youth—clearly shows that "flavored ENDS pose a significant risk to youth."

In light of the risk of flavored ENDS to youth, the TPL Review explained that the FDA reviewed Drip More's application for "any acceptably strong product-specific

[3] The TPL Review generally uses the term "flavored" product to refer to flavors other than tobacco, such as fruit and candy, recognizing that tobacco is technically also a flavor.

evidence" demonstrating a "benefit to a flavored ENDS product over a tobacco-flavored variety" in smoking cessation or reduction effect. The TPL stated that "[c]onsistent with [the TCA], evidence generated using either a[] [randomized controlled trial] design or longitudinal cohort study design is mostly likely to demonstrate such a benefit, although other types of evidence could be adequate if sufficiently reliable and robust, and will be evaluated on a case-by-case basis."

On November 15, 2021, Drip More timely petitioned for review.

II. STANDARD OF REVIEW

"Under the Tobacco Control Act's judicial review provision, a party subject to a marketing denial order may petition for review either in the D.C. Circuit or in the circuit in which its principal place of business is located." *Lotus Vaping*, 73 F.4th at 661 (simplified) (citing 21 U.S.C. § 387*l*(a)(1)(B)). We review marketing denial orders subject to the APA, which requires us to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

Under this "narrow standard of review," we do not substitute our own judgment for that of the agency. *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 16 (2020). Instead, we consider only "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (simplified). An agency "must examine the relevant data and articulate a satisfactory explanation for its action," *id.*, and we must judge the

agency's action "solely by the grounds invoked by the agency" when it took the action, *Sec. & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 196 (1947) ("*Chenery II*").

III. DISCUSSION

A.

1.

Drip More first argues that the FDA acted arbitrarily and capriciously in denying the applications based on Drip More's failure to provide comparative efficacy evidence, resulting in the FDA effectively ignoring other relevant evidence in the applications. In *Wages*, the Supreme Court explained that the FDA's "comparative-efficacy requirement . . . called on manufacturers to compare the health effects of their dessert-, candy-, and fruit-flavored products to those of tobacco-flavored products." 604 U.S. at 578. Drip More does not claim that it offered such evidence, but instead argues that the FDA should not have applied such a requirement to Drip More's application, in light of other components of that application: (1) Drip More's marketing plan, (2) Drip More's contractual requirements for distributors and retailers, and (3) Drip More's online sales data for May through November 2018. Drip More also faults the FDA for failing to address certain information that was not part of the application, namely, (4) the FDA's NYTS results as relevant to Drip More.[4]

[4] Drip More's applications also included a cross-sectional survey of consumers, which the FDA in its TPL Review found to be inadequate to show a benefit to adult smokers. The FDA explained that the survey did not "evaluate the specific products in the applications; evaluate product switching or cigarette reduction resulting from use of these products over

This Court has previously upheld the FDA's denial of premarket applications for failure to satisfy a comparative efficacy requirement. In *Lotus Vaping*, we addressed the FDA's denial of manufacturers' premarket applications in September 2021, the month preceding the FDA's denial of Drip More's applications, based on failure to meet the comparative efficacy standard. *See* 73 F.4th at 666–67. We considered "whether the FDA has statutory authority to require manufacturers to demonstrate that their flavored electronic nicotine delivery systems . . . better promote smoking cessation than comparable tobacco-flavored products, and whether the agency arbitrarily or capriciously denied Petitioners' applications." *Id.* at 661. We held that the text of the TCA "plainly authorizes" the FDA to require such comparative evidence. *Id.* We also determined that the FDA did not act arbitrarily and capriciously in denying the manufacturers' applications, observing that the FDA's rationale was consistent with previous agency guidance, and that the manufacturers "stumbled at the initial hurdle of providing useful comparative evidence demonstrating the risks and benefits of initiation and cessation."[5] *Id.* at 672.

time; or evaluate these outcomes based on flavor type to enable comparisons between tobacco and other flavors." Drip More's opening brief did not challenge this finding or otherwise address the cross-sectional survey. We decline to address Drip More's argument, raised for the first time in its reply brief, that this survey established a low risk to youth. *See Transamerica Life Ins. Co. v. Arutyunyan*, 93 F.4th 1136, 1146 (9th Cir. 2024) (arguments not developed in the argument section of an appellant's opening brief are forfeited).

[5] *See also Liquid Labs LLC v. U.S. Food & Drug Admin.*, 52 F.4th 533, 542 (3d Cir. 2022) ("We also join our sister circuits in concluding that the FDA permissibly required a comparison of a manufacturer's flavored products with tobacco-flavored ENDS products in their ability … to assist adult smokers to quit or switch." (simplified) (collecting cases)).

We further held that any error committed by the FDA in ignoring the petitioners' plans for marketing and for sales access restrictions was harmless. *Id.* at 673.

Two years later in *Wages*, the Supreme Court addressed similar challenges to FDA denials made around the same time as the denial of Drip More's applications and based on similar rationales. *See Wages*, 604 U.S. at 562. The manufacturers in that case asserted that the FDA acted arbitrarily and capriciously in imposing a comparative efficacy requirement, arguing that such a requirement conflicted with the FDA's pre-decisional guidance. *See id.* The Fifth Circuit sitting en banc, in contrast to our opinion in *Lotus Vaping*, agreed with this argument. *See Wages & White Lion Invs., LLC v. Food & Drug Admin.*, 90 F.4th 357, 362–63 (5th Cir. 2024) (en banc).

The Supreme Court disagreed with the manufacturers and with the Fifth Circuit. Addressing the manufacturers' contention that the FDA's comparative efficacy requirement constituted a change in position, the Supreme Court first explained that such a requirement should have come as no surprise because of its basis in the text of the TCA:

> To start, the TCA expressly contemplates comparisons of different tobacco products. It requires an applicant to provide "full reports of all information . . . concerning investigations which have been made to show . . . whether its tobacco product *presents less risk than other tobacco products*." 21 U.S.C. § 387j(b)(1)(A) (emphasis added). Moreover, the FDA's determination that a new tobacco product is "appropriate for the protection of the public

> health" is an inherently comparative judgment. The FDA must account for the "increased or decreased likelihood that existing users of tobacco products will stop using such products" and the "increased or decreased likelihood that those who do not use tobacco products will start using such products." § 387j(c)(4). This balancing test calls out for various types of comparisons, including comparisons between new tobacco products and those that are already available, as well as between different types of new tobacco products that may attract new smokers.

Wages, 604 U.S. at 578–79 (simplified). The Supreme Court then determined that the FDA's denial orders "did not contradict any previously announced position with respect to the comparative effects of differently flavored products." *Id.* at 580. The Supreme Court further stated that "even assuming the predecisional guidance did not perfectly predict the comparative-efficacy standard ultimately applied to applications, the FDA was not required to issue such guidance in the first place." *Id.* at 582. Instead, "the FDA had discretion to work out the meaning of the TCA's comparative standard when evaluating premarket tobacco product applications." *Id.*

The Supreme Court did not reach the merits of the Fifth Circuit's separate determination that the FDA had changed position regarding the submission of marketing plans, a determination that the FDA did not contest in that case; instead, the Supreme Court held that the Fifth Circuit had applied the wrong standard for harmless error. *Id.* at 590.

The Supreme Court vacated the Fifth Circuit's opinion and remanded the case for further proceedings. *Id.* at 592.

2.

Taken together, *Wages* and *Lotus Vaping* limit the arguments available to a manufacturer like Drip More seeking to challenge the FDA's denial of a premarket application for failure to submit comparative evidence. At oral argument, when asked how our decision in *Lotus Vaping* applies to this case, Drip More's counsel responded:

> We're not arguing that the comparative efficacy standard is not relevant. We're not arguing that they didn't have authorization or authority to apply it. We are only arguing, in terms of arbitrary and capricious, that in this case—and it wasn't the case in *Lotus* —we have substantial evidence that minors were not interested in this product. And therefore, it was arbitrary and capricious for FDA not to ask the question: is the comparative efficacy test relevant here? . . . [T]he comparative efficacy test . . . exists . . . because they're assuming this high risk. But we have evidence here that maybe there's not a high risk.

Drip More similarly argues in its opening brief that "the *Lotus* decision turned solely on FDA's failure to consider petitioners' marketing plan and sales restrictions. The Court did not have before it additional evidence, as it does here, demonstrating that minors are not, in fact, using Drip More products."

In evaluating this argument, we begin with the FDA's discussion of risk to youth in its TPL Review of Drip More's application. In that document, the FDA explained that "ENDS are now the most commonly used type of tobacco product among youth[,]" noting that in 2020, approximately 19.6% of U.S. high school students and 4.7% of middle school students were current users of ENDS. Most of those youth report using a *flavored* ENDS product. Data from the 2020 NYTS reflect that among ENDS users, 84.7% of high school students and 73.9% of middle school users reported using a flavored product. Youth ENDS users were more likely to use flavored ENDS products compared to adult users. The FDA explained that flavors also influence youth initiation of ENDS use; data from 2016–17 reflected that 93.2% of youth ENDS users reported that their first ENDS product was flavored, compared to 52.9% among users 25 and older. When asked to indicate their reasons for using ENDS, youth users consistently selected flavor as a top reason. The FDA noted that "within the ENDS category, there is variability in the popularity of device types among youth," and that "the preference for device types and popularity of certain styles is likely fluid and affected by the marketplace," but that the "role of flavor" across device types was "consistent." The FDA further discussed that youth and young adult brains "are more vulnerable to nicotine's effects than the adult brain due to ongoing neural development," and that among youth who use ENDS, "there is a risk of progression to other tobacco products of generally greater health risk." The FDA concluded that the evidence demonstrates that "flavored ENDS pose a significant risk to youth."

Drip More does not appear to take issue with any of the foregoing as a general matter, but argues that in light of Drip

More's substantial evidence that minors were not interested in Drip More's *particular* products, it was arbitrary and capricious for the FDA to require comparative efficacy evidence from Drip More. Drip More refers to two items of evidence. The first is a ten-page spreadsheet, entitled "Drip More Consumer Sales Data 2018," that appears to list persons who placed orders with Drip More during a roughly 6-month period between May 10, 2018 and November 26, 2018. The spreadsheet lists "order time," as well as the name, location, date of birth (all redacted), and the age of the party placing the order. The first page of the spreadsheet contains a row stating that the "median age" is 34. Drip More represents, and the FDA does not dispute, that this spreadsheet reflects Drip More's online sales data for approximately 650 purchases between May and November 2018, with no purchasers under the then-legal age of 20.[6] The second item of evidence to which Drip More refers is the FDA's NYTS data, which were not a part of Drip More's application, but portions of which the FDA cited in its TPL Review. Drip More states, and the FDA does not dispute, that within those survey results "no underage respondent in 2018, 2019, 2020, or 2021 reported having used a Drip More product."

Neither of these establishes that the FDA acted arbitrarily and capriciously here. It is unsurprising that Drip More's online sales data does not include illegal sales to purchasers that Drip More knows to be underage. As the FDA has explained, "many youth obtain their ENDS products from friends or sources in their social networks" or

[6] The legal age for purchasing tobacco products was raised from 18 to 21, effective December 2019. *See* Pub. L. No. 116-94, § 603(a)(1), 133 Stat. 2534, 3123 (2019).

on a "secondary market." *See* FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry* 45 (2020) ("2020 Guidance"); *see also Lotus Vaping*, 73 F.4th at 675 (referring to FDA's determination that marketing restrictions "were ineffective in preventing youth use because children maintained a steady stream of access to the flavored products they desired through alternate means, like their friends and social networks"). Likewise, the failure of youth respondents to specifically write in Drip More's brand name in their survey responses does not undermine the FDA's findings that flavored ENDS—which include the type of product sold by Drip More—pose a significant risk to youth. Although Drip More may have a lower market share or lesser name recognition relative to certain competitors, it has offered no evidence or explanation to distinguish the risk posed by its flavored ENDS. It does not argue, for example, that an offering such as its Candy King Berry Dweebz is by its nature attractive to adults but not interesting to youth.

3.

Drip More also contends that the FDA acted arbitrarily and capriciously in its handling of Drip More's marketing plan and sales access restrictions, asserting that the FDA "completely ignored" this evidence "without adequate explanation." We are not persuaded. The FDA did explain in its TPL Review its reasons for not addressing Drip More's marketing plan.

At the outset, the FDA acknowledged that "limiting youth access and exposure to marketing is a critical aspect of product regulation." The FDA continued:

> It is theoretically possible that significant mitigation efforts could adequately reduce youth access and appeal such that the risk for youth initiation would be reduced. However, to date, none of the ENDS [premarket applications] that FDA has evaluated have proposed advertising and promotion restrictions that would decrease appeal to youth to a degree significant enough to address and counter-balance the substantial concerns, and supporting evidence, discussed above regarding youth use. Similarly, we are not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use ENDS.

Because Drip More had not submitted comparative efficacy evidence establishing a benefit to its flavored ENDS products, the FDA determined that "for the sake of efficiency, the evaluation of the marketing plans in applications will not occur at this stage of review, and we have not evaluated any marketing plans submitted with these applications." In other words, the FDA treated what the Supreme Court referred to as the "comparative-efficacy

requirement," *Wages*, 604 U.S. at 578, as precisely that—a requirement.[7]

Additionally, any error was harmless. In *Lotus Vaping*, we addressed the manufacturers' contentions that the FDA failed to consider their marketing and sales-access-restrictions plans, and without finding error, determined that any error would be harmless. 73 F.4th at 673. We explained that "an error is harmless if it had no bearing on the procedure used or the substance of the decision reached." *Id.* (simplified). Applying this standard, we determined that "at the time the FDA reviewed Petitioners' applications, it had already concluded that eliminating marketing aimed at youth users and monitoring retailers' sales were ineffective in preventing youth use because children maintained a steady stream of access to the flavored products they desired through alternate means, like their friends and social networks." *Id.* at 675 (citing 2020 Guidance at 44–45). Following the analysis of the Second, Third, Fourth, and D.C. Circuits—and consistent with a subsequent opinion by the Tenth Circuit—we determined that any error was harmless where the manufacturers failed to identify material differences between their own proposals and measures the FDA had found inadequate.[8] Drip More has not undertaken

---

[7] *See also Avail Vapor, LLC v. U.S. Food & Drug Admin.*, 55 F.4th 409, 425 (4th Cir. 2022) ("The FDA did not act arbitrarily and capriciously in declining to review Avail's marketing plan. … FDA determined that Avail could not show its products were appropriate for the protection of the public health, and no marketing plan could rectify that baseline infirmity.").

[8] *See Elec. Clouds, Inc. v. U.S. Food & Drug Admin.*, 94 F.4th 950, 967 (10th Cir. 2024) ("Because [the applicants] had already failed to present adequate scientific evidence, their marketing plans couldn't have

to articulate any such differences either. Drip More argues that "it is not clear how this Court could even determine whether Drip More's proposed measures were materially different than those previously considered by the FDA," but our decision in *Lotus Vaping* cited the FDA's consideration of proposed age verification requirements and sales restrictions in its 2020 Guidance, and Drip More has had

---

salvaged their applications."); *Magellan Tech., Inc. v. U.S. Food & Drug Admin.*, 70 F.4th 622, 631 (2d Cir. 2023) ("Magellan does not explain how its marketing strategies differ from the similar measures the FDA had uniformly rejected or why conditions had changed such that the measures would now be effective. Thus, Magellan has not shown that the FDA would have reached a different result had it reviewed Magellan's marketing plan."); *Avail Vapor,* 55 F.4th at 426 ("Avail's marketing plan might have aided its application by presenting novel access restrictions beyond those that the FDA previously determined were not working. Instead, Avail's plan focused solely on age verification and avoiding marketing that would make its products attractive to youth. This was insufficient."); *Liquid Labs*, 52 F.4th at 544 ("Because Liquid Labs has not shown that its marketing plans differ from those previously rejected or that its plans would have rectified the scientific deficiencies, the marketing plans would not change the result."); *Prohibition Juice Co. v. U.S. Food & Drug Admin.*, 45 F.4th 8, 25 (D.C. Cir. 2022) (finding that any error was harmless where "[t]he manufacturers fail to explain why their proposals will prevent youth access where other, similar measures did not").

In contrast to these cases, the Eleventh Circuit in *Bidi Vapor LLC v. U.S. Food & Drug Admin.*, 47 F.4th 1191 (11th Cir. 2022), concluded that it was arbitrary and capricious for the FDA to decline to consider an applicant's marketing plan, and that such error was not harmless. *Id.* at 1205–06. In *Lotus Vaping*, we distinguished that case as involving measures not included in the FDA's 2020 Guidance, such as "Trace/Verify technology" and counterfeit prevention systems, that the FDA found were ineffective to counterbalance the risk of youth use. 73 F.4th at 675 (quoting *Bidi Vapor*, 47 F.4th at 1205). Other circuits have distinguished *Bidi Vapor* on similar grounds. *See Elec. Clouds*, 94 F.4th at 968; *Avail Vapor*, 55 F.4th at 417–18.

ample opportunity to make the case that its own plans are different. 73 F.4th at 674.

Drip More argues that our analysis of harmless error in *Lotus Vaping* is "now in serious doubt" as a result of the Supreme Court's decision in *Wages*. We disagree. In *Wages*, the Supreme Court affirmed that "[w]hen it is clear that the agency's error 'had no bearing on the procedure used or the substance of the decision reached,' a remand would be pointless." 604 U.S. at 590 (quoting *Mass. Trustees of E. Gas & Fuel Assocs. v. United States*, 377 U.S. 235, 248 (1964) (simplified)). The Supreme Court described this was one exception to the so-called "remand rule," *id.* at 590, under which "an agency action cannot stand 'unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained[,]'" *id.* at 587 (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943)). This was the doctrine that we applied in *Lotus Vaping* to find harmless error in that case, and there is no basis for a different outcome here.[9]

4.

Drip More additionally argues that the FDA acted arbitrarily and capriciously because it failed to consider reasonable alternatives to agency action. According to Drip More, "Congress explicitly instructed FDA on how to proceed when a particular ENDS is APPH[,] but there is a risk that youth might eventually begin using the product," in that "the TCA allows FDA to withdraw a[] [marketing granted order] if evidence demonstrates the product is no longer APPH." Drip More argues that the FDA failed to

[9] Drip More does not undertake to identify anything about its marketing or sales-access-restriction plans that would warrant a different result.

address "the possibility of post-authorization surveillance (if Drip More's ENDS are found to be APPH)." But this argument overlooks the FDA's determination that Drip More failed to establish that its products are indeed "appropriate for the protection of the public health." As such, Drip More's products were not eligible for approval even with the possibility of "post-authorization surveillance."

5.

Finally, Drip More argues that the FDA's denial order was erroneous because it extended to fourteen of Drip More's products that have "zero nicotine" options—products that Drip More maintains are outside the scope of the TCA. We disagree.

The TCA generally requires an applicant to receive authorization from FDA before marketing any "new tobacco product." 21 U.S.C. § 387j(a)(2). The TCA defines "tobacco product" to include "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product." *Id.* § 321(rr)(1). These components or parts include the materials "intended or reasonably expected to be used with or for the human consumption of a tobacco product[,]" 21 C.F.R. § 1140.3, such as flavored e-liquids that are intended or reasonably expected to be mixed with nicotine. As the FDA explained in its TPL Review, "where a 'zero nicotine' or 'nicotine free' e-liquid (e.g., a zero nicotine flavored e-liquid) is intended or reasonably expected to be mixed with liquid nicotine, that e-liquid may be a component or part of a tobacco product and subject to FDA's tobacco control authorities."

Drip More asserts on appeal that it "does not intend for its zero-nicotine products to be mixed with nicotine or tobacco" and thus these products are not subject to the TCA at all, but these assertions are belied by the representations Drip More made in its applications. Drip More's applications demonstrated that its "zero nicotine" products were covered by the TCA. For example, Drip More applied for FDA approval for "Candy King Lemon Drops" in three nicotine concentrations: 0mg/ml, 3 mg/ml, and 6 mg/ml. Drip More's application explained:

> The Candy King Lemon Drops 0mg, 3mg, 6mg 100ml is an e-liquid that contains tobacco-derived nicotine and is intended for use in open-system (refillable) electronic nicotine delivery systems (ENDS). The Candy King Lemon Drops 0mg, 3mg, 6mg 100ml is marketed to adult tobacco users for nonmedicinal or nontherapeutic use. Therefore, the Candy King Lemon Drops 0mg, 3mg, 6mg 100ml meets the definition of a tobacco product as set forth in section 201(rr) of the Food, Drug and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (TCA).

Drip More's applications state that each of the concentrations of its product "is intended for use in open-system (refillable) electronic nicotine delivery systems," and "meets the definition of a tobacco product as set forth in section 201(rr)" of the TCA.

The FDA did not err in accepting Drip More's representations that the zero-nicotine concentrations of Drip

More's products were "tobacco products," and for the reasons previously stated, did not act arbitrarily and capriciously in requiring comparative efficacy evidence for Drip More's products.

B.

Drip More next contends that the FDA's application of the comparative efficacy requirement to deny Drip More's premarket applications violated the TCA and the APA, because the FDA was only able to impose such a requirement through notice-and-comment rulemaking. Drip More argues that the comparative efficacy requirement amounted to a "tobacco product standard" governed by 21 U.S.C. § 387g, a rulemaking provision in the TCA separate from the adjudication provision at 21 U.S.C. § 387j.

The Supreme Court in *Wages* declined to address a similar argument, explaining that it had not granted certiorari on the question and did not have adequate briefing. 604 U.S. at 566. But the Supreme Court also set forth the rule governing the question:

> Unless Congress has specified otherwise, agencies are generally free to develop regulatory standards "either by general [legislative] rule or by individual order" in an adjudication. [*Chenery II*,] 332 U.S. [at] 202–203[.] Of course, if a statute requires rulemaking, the affected agency must comply.

Id. at 565. That is, absent some statutory direction to the contrary, the fact that an agency *may* promulgate a regulatory standard through rulemaking does not mean that

an agency *must* engage in rulemaking to apply that standard in a given case. Accordingly, we address whether the TCA specifies that the FDA, in order to apply the comparative efficacy requirement to Drip More, was first required to engage in statutory rulemaking. Looking at the text of the TCA, including as interpreted by the Supreme Court in *Wages* and this Court in *Lotus Vaping*, we conclude that it does not.

As discussed in the previous section, we determined in *Lotus Vaping* that the FDA's comparative efficacy requirement was "plainly authorized" by the text of the TCA—specifically, the *adjudication* provisions of 21 U.S.C. § 387j. *See* 73 F.4th at 661. We explained:

> We start with the text of the Tobacco Control Act. *See Van Buren v. United States*, [593 U.S. 374, 381] (2021). The Act permits the FDA to authorize the marketing of a new tobacco product only if the manufacturer has established that it "would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). In making that determination, the FDA must consider "the *increased or decreased likelihood* that existing users of tobacco products will stop using such products," as well as "the *increased or decreased likelihood* that those who do not use tobacco products will start using such products." *Id.* § 387j(c)(4) (emphases added). These considerations are inherently comparative. *See Avail Vapor*, 55 F.4th at 428.

> The textual support for the FDA's authority does not end there. Congress also directed applicants seeking to market a new tobacco product to include in their applications "full reports of all information . . . concerning investigations which have been made to show the health risks of such tobacco product and *whether such tobacco product presents less risk than other tobacco products*." 21 U.S.C. § 387j(b)(1)(A) (emphasis added). Section 387j(c) provides, in turn, that the FDA "shall deny an application . . . if, upon the basis of the information submitted"—which would necessarily include any comparative reports submitted in accordance with § 387j(b)(1)(A)—"and any other information before the [FDA]," the agency finds that the applicant did not show "that permitting [the] tobacco product to be marketed would be appropriate for the protection of the public health." *Id.* § 387j(c)(2)(A). Put differently, the FDA must weigh the risk of hooking new users on tobacco products against a product's potential to help existing users switch from unhealthier forms of tobacco—i.e., combustible cigarettes. *See Gripum* [*LLC, v. FDA*], 47 F.4th [553,] 555 [(7th Cir. 2022)].

Id. at 669.[10] In other words, far from specifying that the FDA may only require such comparative efficacy data after

[10] Two years later in *Wages*, the Supreme Court relied on the same paragraphs within the adjudication provision of the TCA, including 21

notice-and-comment rulemaking under Section 387g, the TCA expressly authorizes the agency to require such data in adjudicating an application under Section 387j. *See also Elec. Clouds*, 94 F.4th at 959 ("Given the statutory language, five federal appellate courts have concluded that the Act supplied adequate notice of the need to compare flavored and unflavored e-liquids.") (collecting cases). This strongly weighs against Drip More's position.

In *Wages*, the Supreme Court cited the same portions of the TCA's adjudication provision in rejecting the manufacturers' argument that the comparative efficacy requirement was inconsistent with the FDA's earlier guidance, stating that "the FDA had discretion to work out the meaning of the TCA's comparative standard when evaluating premarket tobacco product applications." 604 U.S. at 582 (citing 21 U.S.C. § 387j(b)(1)(A), (c)(4)). The Supreme Court explained that "[a] contrary rule would be in tension with *Chenery II*'s teaching that, absent a statutory prohibition, agencies may generally develop regulatory standards through either adjudication or rulemaking." *Id.* The Supreme Court added that "the FDA was not required to issue such guidance in the first place." *Id.* These statements are also a strong indication that the TCA authorizes the FDA to develop a comparative efficacy requirement through adjudication.

U.S.C. § 387j(b)(1)(A) and (c)(4), to describe the FDA's review of an application as an "inherently comparative judgment," involving a balancing test that "include[s] comparisons between new tobacco products and those that are already available, as well as between different types of new tobacco products that may attract new smokers." 604 U.S. at 578, 579.

Against this backdrop, the language of the "tobacco product standards" rulemaking section of the TCA, 21 U.S.C. § 387g(c)(1), does not compel a different result. Section 387g's language allowing for the FDA's promulgation of additional tobacco product standards is permissive rather than mandatory: the Secretary "*may* adopt tobacco product standards . . . if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health." (a)(3)(A) (emphasis added). This permissive language contrasts with other provisions of the TCA stating that the FDA "shall" issue regulations or guidance on certain topics. *See* 21 U.S.C. §§ 387e(j)(3)(B) (FDA "shall issue" regulations with respect to "substantially equivalent" tobacco products), 387k(*l*)(1) (FDA "shall issue regulations or guidance" with respect to review of "modified risk tobacco products"). Where the FDA chooses to promulgate a tobacco product standard, the TCA specifies applicable procedures and appropriate content. *See* 21 U.S.C. § 387g(a)(4), (c). However, nothing in this specification of rulemaking content purports to constrain what types of evidence the FDA may require in adjudicating an application. Indeed, nothing within Section 387g on its face purports to divest or circumscribe the FDA's adjudication authority under Section 387j.[11]

[11] In rejecting a similar argument that the FDA was required to engage in rulemaking, the Seventh Circuit determined that "Congress's intent to allow the FDA to develop its premarket policy through a flexible, case-by-case adjudicative approach is apparent in the structure of the Act." *Gripum,* 47 F.4th at 559. While the TCA "obligates the agency to issue interpretative rules and regulations in some contexts," *id.* (citing 21 U.S.C. §§ 387e(j)(3)(B) and 387k(*l*)(1)), "in the premarket-adjudication

Additionally, the comparative efficacy requirement bears little resemblance to the tobacco product standards established in the statute, referred to as "special rules." *See* § 387g(a)(1) (providing "special rules"), (a)(2) (describing the "special rules" as "tobacco product standards"). These standards relate to banning certain flavors in combustible cigarettes, (a)(1)(A), or banning pesticide chemical residue above a certain level, (a)(1)(B). The comparative efficacy requirement is qualitatively different from the existing

---

context of section 387j(c), there is no such obligation for the FDA to promulgate implementing regulations."

Although not cited in Drip More's briefing, we are aware that the Fifth Circuit in *R.J. Reynolds Vapor Co. v. Food & Drug Administration*, 65 F.4th 182 (5th Cir. 2023), in granting a stay pending review of the FDA's denial of an application for flavored ENDS, determined that the manufacturer was "likely to show that the FDA has instituted a de facto ban on non-tobacco-flavored e-cigarettes without going through notice-and-comment." *Id.* at 194. This decision is difficult to square with *Wages*, however, which emphasized the FDA's discretion to develop and apply comparative efficacy standards through adjudication. *See* 604 U.S. at 578–79. Additionally, the Fifth Circuit's conclusion was based on its determination that an FDA memorandum issued on July 9, 2021, known as the "fatal flaw" memorandum, amounted to de facto rulemaking requiring notice and comment under the APA, where "not a single [premarket application] for non-tobacco-flavored e-cigarettes has been granted." 65 F.4th at 193 ("We conclude that the Fatal Flaw memo's heightened evidentiary standard 'bears all the hallmarks' of a substantive rule." (simplified)). However, the Supreme Court's subsequent decision in *Wages* observed that the memorandum was superseded and was never rigidly enforced, and rejected the manufacturers' arguments that FDA secretly applied the standards in that memorandum. *See* 604 U.S. at 577 ("Agencies are entitled to a presumption of regularity, and the record offers enough support for us to conclude that the FDA never enforced a rigid 'fatal flaw' standard.") (simplified). In the wake of *Wages*, Drip More has not argued that the "fatal flaw" memorandum enunciated a rule that was applied here.

tobacco product standards; the "special rules" impose restrictions on the manufacturing of tobacco products, while the comparative efficacy requirement addresses evidence needed to support a manufacturer's application for its ENDS products. *See VDX Distro, Inc. v. U.S. Food & Drug Admin.*, 179 F.4th 356, 365–66 (5th Cir. 2026) (rejecting manufacturers' argument that the comparative efficacy requirement is a "tobacco product standard" requiring rulemaking; unlike a tobacco product standard, the FDA's comparative efficacy requirement "channels the flexible adjudicatory discretion that a tobacco product standard would usurp").

Drip More argues that the FDA's comparative efficacy requirement nonetheless amounts to "de facto" rulemaking requiring notice and comment under the APA. Drip More quotes *MacLean v. Dep't of Homeland Sec.*, 543 F.3d 1145 (9th Cir. 2008), in which we stated that "[a]n agency adjudication may require a notice and comment period if it constitutes de facto rulemaking that 'affects the rights of broad classes of unspecified individuals.'" *Id.* at 1151 (quoting *Yesler Terrace Cmty. Council v. Cisneros*, 37 F.3d 442, 448 (9th Cir. 1994)). This authority does not help Drip More. In *MacLean*, we determined that the adjudicative order at issue, in which the Transportation Security Agency determined that a message constituted "sensitive security information," did not affect the rights of a broad class of people, and that no notice and comment period was required. *Id.* at 1152. *MacLean* cited our decision in *Cisneros*, which explained at greater length:

> Two principal characteristics distinguish rulemaking from adjudication. First, adjudications resolve disputes among

> specific individuals in specific cases, whereas rulemaking affects the rights of broad classes of unspecified individuals. *See United States v. Florida E. Coast Ry.*, 410 U.S. 224, 244–45 (1973); *Ford Motor Co. v. FTC*, 673 F.2d 1008, 1010 (9th Cir. 1981), *cert. denied* 459 U.S. 999 (1982). Second, because adjudications involve concrete disputes, they have an immediate effect on specific individuals (those involved in the dispute). Rulemaking, in contrast, is prospective, and has a definitive effect on individuals only after the rule subsequently is applied. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 216–17 (1988) (the "central distinction" between rulemaking and adjudication is that rules have legal consequences "*only* for the future") (Scalia, J., concurring) (emphasis added); *Prentis v. Atlantic Coast Line Co.*, 211 U.S. 210, 226 (1908).

37 F.3d at 448. Here, the FDA's denial of Drip More's applications had an effect only on Drip More, not on a broad class of unspecified individuals; and its effect was immediate upon denial, rather than being applied only to future cases.

Drip More also cites without analysis *NLRB v. Bell Aerospace Co.*, 416 U.S. 267 (1974), in arguing that the FDA's reliance on adjudication was an abuse of discretion; but that case reiterated that an agency "is not precluded from announcing new principles in an adjudicative proceeding and that the choice between rulemaking and adjudication lies

in the first instance within the [agency's] discretion," and found no abuse of that discretion. *Id.* at 294.

Drip More argues that the FDA has issued denial orders for over 99% of applications for non-tobacco flavored ENDS, reflecting a level of uniformity consistent with rulemaking. Drip More further states that as of the date of filing its opening brief, "FDA has issued Marketing Granted Orders ('MGOs') for only 39 ENDS products, only six of which were for non-tobacco flavored ENDS (i.e., menthol flavored products)." More recently, the FDA authorized the marketing of four additional ENDS products in menthol, mango, and blueberry flavors; but the fact remains that the FDA has denied most of the applications for non-tobacco flavored ENDS. Uniformity or near-uniformity does not, however, necessarily transform adjudication into rulemaking. And these statistics do not transform a requirement for comparative efficacy evidence into a ban on non-tobacco flavors. At oral argument, when asked whether any of the applicants submitted evidence in an effort to show comparative efficacy, counsel for Drip More responded that applicants submitted such evidence in ten cases, and that in each of those cases the FDA issued a marketing granted order. This further supports that the FDA's requirement of comparative efficacy evidence, consistent with the TCA's direction to require comparative evidence in adjudicating an application, is not a ban in disguise.

IV. CONCLUSION

The FDA's denial of Drip More's premarket applications based on failure to provide evidence of comparative efficacy was not arbitrary and capricious. Any error in declining to consider Drip More's plans for marketing and access restrictions was harmless. The FDA was not required to

engage in notice-and-comment rulemaking, under either the TCA or the APA, before applying a comparative efficacy requirement to deny Drip More's application.

DENIED.