No. 23-1038

IN THE
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION,

Petitioner,

v.

WAGES AND WHITE LION INVESTMENTS, L.L.C., DBA TRITON DISTRIBUTION, ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

BRIEF OF R.J. REYNOLDS VAPOR COMPANY, *ET AL.* AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Amici R.J. Reynolds Vapor Co., RJR Vapor Company, L.L.C. (together, "Reynolds" or "RJRV"), Avail Vapor Texas, L.L.C., and Mississippi Petroleum Marketers and Convenience Stores Association submit this brief because the Fifth Circuit correctly adjudicated a question of great practical importance to all manufacturers and retailers of e-cigarettes: whether Petitioner FDA acted arbitrarily and capriciously in changing its position on the authorization requirements for e-cigarettes after the deadline for submitting applications had passed. RJRV is among the many applicants who spent considerable time and money preparing applications following then-existing regulatory guidance—in its case, for menthol-flavored products as well as other flavors—only to discover after it was too late that FDA had changed its approach in a way that prompted FDA to deny the applications. *See R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182 (5th Cir. 2023) ("*RJRV Vibe*"); *R.J. Reynolds Vapor Co. v. FDA*, No. 23-60128 (5th Cir. Mar. 29, 2023) (stay order); *R.J. Reynolds Vapor Co. v. FDA*, No. 23-60545 (5th Cir. Feb. 2, 2024) (stay order).

SUMMARY OF ARGUMENT

FDA's denial orders for Respondents' premarket applications (like for *amici*'s) were the culmination of years of agency missteps, including shifting deadlines and secretly evolving substantive requirements that

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[1] No counsel for a party authored this brief in whole or in part, and no person other than *amici curiae* and their counsel made any monetary contribution intended to fund the preparation or submission of this brief.

left applicants in the dark about what FDA expected from them. The Agency's changing positions on what evidence it would require to grant marketing authorization violated basic principles of fair notice and reasoned decisionmaking. And the context in which those reversals occurred underscores their arbitrariness.

At the same time, FDA's denial orders for *menthol*-flavored e-cigarettes present distinct issues from the other-flavored products at issue here, so the Court should make clear that it is not addressing menthol. As Congress, FDA, and public-health experts have repeatedly recognized, menthol is unique among flavors. Indeed, FDA's own scientists unanimously recommended authorizing menthol-flavored e-cigarettes as appropriate for the protection of the public health—only to be reversed by a new and single-minded appointee. Thus, if this Court were to uphold Respondents' denial orders (it should not), denial orders for menthol-flavored products would still face additional obstacles, and the Court's opinion should take care to avoid those distinct issues.

ARGUMENT

I. FDA'S MISHANDLING OF RESPONDENTS' APPLICATIONS WAS THE CULMINATION OF YEARS OF AGENCY MISSTEPS.

This case is the result of a regulatory fiasco stemming from FDA's ever-shifting approach to bringing e-cigarettes under the ambit of the Family Smoking Prevention and Tobacco Control Act (TCA), P.L. 111-31, 123 Stat. 1776 (June 22, 2009). Those shifts in both timetables and substantive

requirements for premarket applications whipsawed manufacturers multiple times over.

A. FDA could not settle on a timetable for premarket applications.

The first aspect of this story is calendrical: ever-shifting deadlines that most everyone outside FDA found intolerable, coupled with FDA's failure to meet statutorily required deadlines to review applications.

1. The TCA gave FDA the authority to regulate certain tobacco products, such as cigarettes and smokeless tobacco. *See* 21 U.S.C. § 387a. The Act also established a premarket authorization process for manufacturers seeking to bring new tobacco products to market after February 15, 2007—products that Congress anticipated would be similar to existing ones (*e.g.*, new kinds of combustible cigarettes). *See id.* § 387j(a)(2). Congress left it to FDA's discretion whether to extend the statute's reach to other tobacco products, such as the then-emerging category of products known as e-cigarettes, which are generally believed to present fewer health risks than combustible cigarettes. *See id.* § 387a(b).[2]

For seven years, FDA did not exercise its authority to regulate e-cigarettes and allowed them to proliferate without oversight. Then, in 2016, FDA issued a sweeping rule that deemed all tobacco-derived products, including e-cigarettes, to be subject to the TCA's requirements. *See Deeming Tobacco*

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[2] This provision, granting unfettered discretion to "deem[]" other tobacco products subject to the statute, has been challenged on nondelegation grounds, *see, e.g., Big Time Vapes, Inc. v. FDA*, 963 F. 3d 436 (5th Cir. 2020), but those arguments are not at issue here.

Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,973, 28,974, 29,028, 29,102 (May 10, 2016). This included the requirement that new products receive FDA authorization before they may be sold.

But because e-cigarettes were already on the market in 2016, FDA's action "created a serious and obvious problem." *Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1134 (5th Cir. 2021) (stay opinion). Suddenly e-cigarettes already on store shelves needed *pre*-market authorization from FDA. But, as FDA recognized, requiring all e-cigarettes to come off the market was at odds with the public health because e-cigarettes could "potentially promote transition away from combusted tobacco use." 81 Fed. Reg. at 29,011.

For this reason, and "[t]o avoid an overnight shutdown of the entire e-cigarette industry, the FDA delayed enforcement of the Deeming Rule." *Wages*, 16 F.4th at 1134. But rather than do so formally—for example, by delaying the effective date to allow for the submission and consideration of applications—FDA declared that it would "exercise enforcement discretion" to allow e-cigarettes to remain on the market until applications could be submitted and processed. 81 Fed. Reg. at 28,977–78.

2. FDA first set a deadline for e-cigarette applications in the 2016 Deeming Rule. 81 Fed. Reg. at 28,977–78. Under the rule, applications for e-cigarettes were due in August 2018. *Id.* at 29,011; *Wages*, 16 F.4th at 1134.

As the applications deadline approached, however, the Agency still had not set up an application review

system. As a result, in May 2017, FDA extended the deadline by three months. FDA, *Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry* at 3, https://tinyurl.com/mr48xy8h (May 15, 2017). But that too turned out not to be enough time to set up a pathway. Just three months later, FDA issued new guidance in which it deferred enforcement as to e-cigarettes through 2022. FDA, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry* (Revised) at 3, https://tinyurl.com/mr4axt37 (Aug. 10, 2017).

FDA's delays did not go unnoticed. In 2019, the American Academy of Pediatrics sued FDA to accelerate these deadlines. *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461 (D. Md. 2019). The district court took a dim view of FDA's conduct: "Through the August 2017 Guidance, the FDA is abdicating its statutory duty to review new tobacco products in the prompt fashion dictated by Congress in its premarket review requirements." *Id.* at 492. The court thus vacated FDA's August 2017 guidance and ordered it to set new, more expeditious deadlines. *See id.* at 498. Then, in July 2019, the court itself set a ten-month deadline for applications for premarket authorization. *See Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019). FDA later said it was independently setting the same deadline of May 2020. J.A. 126–240 (FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems: Guidance for Industry*, 85 Fed. Reg. 23,973 (Apr. 30, 2020)

(hereinafter *Enforcement Priorities*)).[3] As a result, instead of the promised years to prepare applications, applicants had just months. Then, the pandemic interrupted the timeline, and, in April 2020, on FDA's motion, the court granted a 120-day extension and set a new (and final) deadline of September 9, 2020. *See* FDA, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Withdrawal of Guidance*, 85 Fed. Reg. 23,968, 23,969 & n.5 (Apr. 30, 2020). Once again, FDA stated that it independently decided to set the deadline for September 2020. J.A. 178.

In sum, FDA shifted the deadline four times, all the while hanging the Sword of Damocles over applicants because their products were on the market without authorization. First, FDA set the deadline for August 2018, then moved it to November 2018, then pushed it to 2022. FDA then reversed course and accelerated the deadline to May 2020, and finally settled on September 9, 2020. These ever-changing deadlines left applicants scrambling.

Compounding the calendrical problem, FDA then missed the statutory deadline for reviewing applications for all major manufacturers. Congress specified that FDA must act on premarket applications "[a]s promptly as possible, but in no event later than 180 days after receipt." 21 U.S.C. § 387j(c)(1)(A). Despite that command, FDA blew past the 180-day deadline for applications from major

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[3] The April 30, 2020 guidance document in the Joint Appendix is a revised version of a document released several months earlier. *See Priorities for Electronic Nicotine Delivery Systems: Guidance for Industry*, 85 Fed. Reg. 720 (Jan. 7, 2020).

manufacturers. In fact, FDA did not issue the first decision on an application from a major manufacturer until more than a *year* after the application deadline—and *two years* after that application had been filed.[4] FDA's turtle-speed led a federal court to order the Agency to file regular status reports on its review process. Revised Remedial Order, *Am. Acad. of Pediatrics v. FDA*, No. 8:18-cv-883 (D. Md. Apr. 15, 2022). Even today, at least one application from a major manufacturer remains pending before FDA more than four years after it was filed. Status Report, *id.* (July 22, 2024). And that doesn't even cover the applications that were initially denied, but which FDA then decided to re-review. *See id.* Thus, while FDA rushed applicants to submit their applications on an accelerated timeline, the Agency has dragged its feet on reviewing those applications, contrary to Congress's express 180-day deadline.

B. FDA's requirements for the authorization process silently evolved until well *after* the application deadline.

Even worse than FDA's shifting deadlines were its secretly evolving substantive standards—standards that continued to shift even *after* the application deadline had passed. As the court below aptly described it, this was "the regulatory equivalent of Romeo sending Mercutio on a wild goose chase—and then admitting there never was a goose while denying he even suggested the chase." Pet. App. 3a.

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[4] FDA, *Premarket Tobacco Product Marketing Granted Orders*, https://tinyurl.com/2fa5zjnf.

1. When FDA brought e-cigarettes under the TCA's regulatory umbrella, FDA had no authorization plan. It wasn't until two years later that FDA offered "guidance" to manufacturers about the Agency's standards and expectations. In particular, FDA explained what manufacturers needed to include (and what they need not include) in their applications.

The first guidance came in October 2018, in the form of a public presentation that FDA later posted on its website. Pet. App. 6a. Addressing what manufacturers should include in applications for e-cigarettes, FDA said that "[n]o specific studies are required" and recommended that applicants "[c]ompare their new tobacco product to a representative sample of tobacco products on the market." *Id.* FDA asked only that applicants "[i]nclude justification for why using evidence or data from other products is appropriate." *Id.* FDA did not suggest trying to offset a flavored product's youth appeal by showing that the product was more effective at getting adults to quit smoking than some other product. Instead, FDA advised that "[y]outh behavioral data"—while "useful"—are "not required at this time." *Id.*

FDA followed that public meeting with a 100-page written guidance in June 2019. J.A. 1–109. In this document, FDA acknowledged that "[g]iven the relatively new entrance of [e-cigarettes] on the U.S. market, … limited data may exist from scientific studies and analyses" and advised that "in general, … [FDA did] not expect that applicants will need to conduct long-term studies to support an application." J.A. 28. Instead, applicants could take other approaches, such as surveying current smokers and potential users of the new products to study the

likelihood that current smokers would switch from combustible cigarettes to the new products, or conducting "observational studies" to determine current smokers' "perception" and "actual use" of the new products. *Id.*

FDA also addressed comparator products. FDA recommended that each applicant choose a comparator product that was interchangeable with the new product. That way applicants could "compare the health risks of [their] product to both products within the same category and subcategory, as well as products in different categories as appropriate." J.A. 30 (2019 Guidance). As FDA explained, "current users may switch to other products within the same category," so the Agency recommended that applicants choose comparator "products that consumers are most likely to consider[ ] interchangeable between your proposed product and other similar products." *Id.*

FDA devoted just two paragraphs to flavors. FDA said that it expected applications would include "scientific reviews" touching on their associated health risks and also descriptions of "research" on their appeal to consumers. J.A. 87–88. FDA, however, said nothing to suggest that manufacturers should produce evidence that their flavored products were better than tobacco-flavored ones at helping adult smokers to quit smoking.

After issuing its detailed guidance, FDA promulgated a proposed application rule in the fall of 2019. *See Premarket Tobacco Product Applications and Recordkeeping Requirements*, 84 Fed. Reg. 50,566 (proposed Sept. 25, 2019). In the rule, FDA repeated what it had already said: FDA "does not expect that

long-term clinical studies (*i.e.*, those lasting approximately 6 months or longer) will need to be conducted for each [application]." *Id.* at 50,619. Again, FDA did not call for manufacturers to show that their flavored e-cigarettes were superior to tobacco-flavored ones in helping adult smokers quit. Instead, it "recommend[ed] the product be compared"—as to "health risks"—only "to other e-liquids used in a similar manner" *Id.* at 50,600. Around the same time, FDA held another public meeting where it restated its prior recommendations, failed to mention any long-term study requirement, and failed to suggest that flavored e-cigarettes should be compared to tobacco-flavored e-cigarettes. Pet. App. 8a-10a.

Around this time, two surveys showed that youth "e-cigarette use [had] hit the highest levels ever recorded." J.A. 141. The CDC associated this spike in youth vaping with the popularity of JUUL, at the time the most popular e-cigarette. *See* Angelica Peebles, *CDC blames spike in teen tobacco use on vaping, popularity of Juul*, CNBC (Feb. 11, 2019), https://tinyurl.com/5xh7kcmn. Also that year, the public-health authorities had received reports of over 2,500 "hospitalizations for lung injuries associated with the use of vaping products, … including 54 confirmed deaths." J.A. 142. (The CDC later concluded that the most likely cause was an ingredient in certain THC-containing vaping products, not nicotine-containing e-cigarettes. CDC, *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, https://tinyurl.com/3cs22ta2.)

These concerns gave rise to political pressure on FDA. *See* Richard Harris, *FDA To Banish Flavored E-Cigarettes To Combat Youth Vaping*, NPR (Sept. 11,

2019). The White House summoned FDA's Commissioner and the HHS Secretary to explain what FDA would do about the rise in youth vaping.

Spurred by the pressure, FDA issued new enforcement guidance in 2020. J.A. 126–240 (*Enforcement Priorities*). FDA said it would focus its enforcement on a few categories of e-cigarettes that FDA believed were popular with youth, including flavored cartridge-based products (meaning those with flavors other than tobacco or menthol). J.A. 129–30. (Respondents' e-cigarettes—flavored e-liquids for open systems—were not among the targeted products.) The 2020 document did not address the content of marketing applications.

By the time the September 2020 deadline for applications arrived, over 500 e-cigarette manufacturers had filed hundreds of thousands of applications covering more than 6.5 million e-cigarettes. *See* Pet. App. 2a; FDA, *FDA Denies Marketing Applications for About 55,000 Flavored E-cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health* (Aug. 26, 2021), https://tinyurl.com/2m98nthj.

2. In the middle of 2021, the political heat on FDA had reached a boiling point. Many politicians thought FDA was still not doing enough to combat youth use of flavored e-cigarettes. For example, on June 23, 2021, a House subcommittee questioned acting FDA Commissioner Janet Woodcock about flavored e-cigarettes. During her testimony, Commissioner Woodcock "agreed" with committee members that "if any flavors are left on the market, kids will flock to them." *See* Press Release, Committee on Oversight

and Accountability Democrats, *Subcommittee Hearing Offers Insight into Future of E-Cigarette Regulation* (June 23, 2021), https://tinyurl.com/2p2kmwy7.

Less than a month later, an associate director from FDA's Office of Science issued an internal, non-public memorandum (commonly referred to as the "Fatal Flaw memo") in which she discarded the Agency's previous guidance and said FDA would reject any application for a flavored e-cigarette (other than tobacco and menthol) if it failed to include long-term studies designed to show that flavors offer some public-health benefit over tobacco-flavored products (presumably increased effectiveness at weaning smokers off cigarettes). *See* J.A. 242–43. This new standard applied across the board: Gone was the distinction from FDA's 2020 guidance between products popular with youth and products that are not. The memo stated that to satisfy the statutory standard—"appropriate for the protection of the public health"—a manufacturer would have to provide "either a randomized controlled trial (RCT) or a longitudinal cohort study." *Id.* at 243. "The absence of these types of studies," she explained, would be "considered a fatal flaw, meaning any application lacking this evidence will likely receive a marketing denial order." *Id.*

The memo went on to say that, "[t]o decrease the number of [applications] without final action by September 9, 2021" (the date on which FDA was scheduled to lift its blanket enforcement discretion for products with timely filed applications), FDA would gather together a set of applications from the largest manufacturers and subject them to "a Fatal Flaw review." *Id.* A Fatal Flaw review, the memo explained,

is "a simple review in which the reviewer examines the submission to identify whether or not it contains the necessary type of studies. The Fatal Flaw review will be limited to determining presence or absence of such studies; it will not evaluate the merits of the studies." *Id.* In other words, it was now the Agency's internal (non-public) policy that any application that omitted information FDA had never mentioned (or even forsworn) in previous guidance was "likely" to end up peremptorily denied without consideration of its merits. And this was so even for products, like e-liquids for open systems, that FDA had identified in its 2020 guidance as not popular with youth.

FDA claims it rescinded the Fatal Flaw memo, but, as Judge Jones noted in her dissent from the panel opinion (which the en banc court subsequently vacated), the memo's "approach appears to have been followed by FDA in denying Respondents' and others' applications in a check-box 'scientific review' form [(reproduced below)] that indicated only whether a[n application] included a randomized controlled trial or longitudinal cohort study." Pet. App. 129a–130a (Jones, J. dissenting).

Presence of Evidence for Flavored ENDS Products

Criterion A	Present		Absent
Randomized Controlled Trial (RCT) on new product use and smoking behavior	☐		☒
Instructions: To select "Present", all of the following boxes must be checked "Yes":	**Yes**	**No**	**N/A[2]**
Was the RCT conducted using new products?	☐	☐	☒
Does the RCT include a tobacco-flavored arm and a flavored product arm[3]?	☐	☐	☒
Do the outcomes include users' ENDS and smoking behavior to assess switching and/or cigarette reduction (e.g., measures of cigarettes per day, smoking cessation, ENDS use)?	☐	☐	☒
Comment(s): N/A			

Criterion B	Present		Absent
Longitudinal Cohort Study (LCS) on new product use and smoking behavior	☐		☒
Instructions: To select "Present", all of the following boxes must be checked "Yes":	**Yes**	**No**	**N/A[2]**
Was the LCS conducted and does it include users of new products who are followed over time?	☐	☐	☒
Was use of tobacco-flavored products and other flavored products assessed[3]?	☐	☐	☒
Do outcomes include users' ENDS and smoking behavior to assess switching and/or cigarette reduction (e.g., measures of cigarettes per day, smoking cessation, ENDS use)?	☐	☐	☒
Comment(s): N/A			

Pet. App. 35a (emphasis added) (depicting FDA assessment of the applications in *Wages*). Perhaps not sensing the irony in their statement, sixteen members of Congress who filed an *amicus* brief in support of FDA now say that "[r]eaching determinations on applications is not a perfunctory box-checking exercise." Br. of Sixteen Members of Congress as *Amici Curiae* in Support of Petitioner at 14. But as Judge Oldham observed: "That sure looks like a requirement that petitioners perform long-term scientific studies on their e-cigarette products …." Pet. App. 36a. Manufacturers had no notice of FDA's internal memo and fatal flaw review process, however, because they did not come to light until years later (as a result of litigation).

The final application rule appeared a few months after the Fatal Flaw memo was issued internally within FDA (and more than a year after applications

were due). *See Premarket Tobacco Product Applications and Recordkeeping Requirements*, 86 Fed. Reg. 55,300, 55,387 (Oct. 5, 2021). Critically, the final rule did not say *anything* about "fatal flaws" or the need for specific studies on flavored e-cigarettes. Instead, FDA reiterated the earlier guidance that "FDA recognizes that this type of long-term epidemiological data is not available for all categories of products and does not expect that long-term clinical studies (*i.e.*, those lasting approximately 6 months or longer) will need to be conducted for each [application] …." *Id.* Also in line with previous guidance, the final rule did not say that FDA expected manufacturers of flavored e-cigarettes to demonstrate that their products are more effective than tobacco-flavored e-cigarettes at helping smokers quit. To the contrary, FDA rejected a commenter's suggestion that it "should impose specific requirements that a flavored tobacco product must meet to receive a marketing granted order." *Id.* at 55,386. FDA said it "declines to create a series of criteria that either all products or a specific subset of products must meet in order for marketing of such products to be considered" appropriate for the protection of the public health. *Id.* FDA explained that there were essentially too "many factors" to offer applicants any view into the Agency's thought process. *See id.*

3. FDA then committed another secret reversal, one that even FDA now tacitly concedes was error. *See* FDA Br. 31. Before applications were due, FDA made clear that information relating to marketing plans would be a "critical" component of applications. Pet. App. 8a. Indeed, the Agency specified the intervals at which it needed manufacturers to provide sales data

and explained that information about marketing plans was needed "to enable FDA to better understand the potential consumer demographic." *Id.* FDA, however, threw those statements out the window when it came time to review applications. Instead, FDA ignored marketing plans, declaring that no marketing restrictions possibly could be adequate for flavored products—despite earlier finding that they worked. Pet. App. 23a. As the Fifth and Eleventh Circuits have recognized, this about-face was arbitrary and capricious. *Id.*; *Bidi Vapor LLC v. FDA*, 47 F.4th 1191, 1203 (11th Cir. 2022). And, in this Court, FDA (at 31) has "not sought review of the Fifth Circuit's threshold finding of error," tacitly conceding the point.

4. One more backroom reversal remained. In July 2022, with many timely filed applications still pending, FDA's Center for Tobacco Products got a new Director: Brian King. *See Logic Tech. Dev. LLC v. FDA*, 84 F.4th 537, 559 (3d Cir. 2023) (Porter, J., dissenting). Immediately upon taking office, King changed FDA's approach to menthol e-cigarettes. FDA's prior guidance had explicitly distinguished between tobacco- and menthol-flavored e-cigarettes on the one hand, and other flavors (like candy or desserts), on the other. As FDA's scientists concluded in 2020, menthol e-cigarettes should be treated differently from other flavors because "[m]enthol is unique compared to other available [e-cigarette] product flavors as it is the only characterizing flavor available in cigarettes." J.A. 170. Thus, "[b]y March 2022, every discipline within the [FDA Office of Science] concluded that [the] menthol products should be approved." *Logic*, 84 F.4th at 558 (Porter, J., dissenting).

But in his internal (non-public) memo dated October 25, 2022, Director King said that, henceforth, menthol would be treated the same as other flavors. As Judge Porter explained, "[w]ithout citing any scientific studies or published articles, he asserted that 'scientific evidence on the role of flavors in youth use of [e-cigarettes] is significantly more rigorous and robust than the preference data concerning menthol combustible cigarette smokers.' Therefore, 'robust evidence of benefit is required to overcome the risk to youth and show that authorizing the marketing of a menthol-flavored [e-cigarette] would be appropriate for the protection of the public health.'" *Id.* (internal citations omitted); *see RJRV Vibe*, 65 F.4th at 191–92. *See generally* Alex Norcia, *Memos Show FDA Overruled Science-Office Call to OK Menthol Vapes*, Filter Magazine (Dec. 14, 2022) (publishing FDA's internal memos), https://bit.ly/3JjjcVi.

5. FDA's ever-shifting requirements stem from its failure to grapple with a basic issue: what the Tobacco Control Act means when it says new products must be "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). Still to this day, FDA has not explained how it interprets this key standard for premarket authorization. *See* Final Application Rule, 86 Fed. Reg. at 55,386.

Not only has FDA's non-answer allowed the Agency to make things up as it goes, it has led to manifest contradictions. For example, FDA has been inconsistent in the proof it requires on each side of its ad hoc balancing of the risk a product poses to youth and the benefit it has for adult smokers seeking to quit smoking. The Agency simply assumes a high risk to youth across the board, regardless of the type of

flavored product at issue. But, in turn, FDA has required applicants to prove a benefit at the level of the particular product, with no possibility of piggybacking on, for example, another company's study of a similar type of e-cigarette. Certainly, no meaningful guidance can be found in slides like this one, which FDA offered in 2021:

FDA Center for Tobacco Products Director Matt Holman, Food and Drug Law Institute, *Tobacco and Nicotine Products Regulation and Policy Conference, Pre-Market Tobacco Applications (PMTAs): Recent Decisions and Surveying the Post-Deadline Landscape* (Oct. 27, 2021).

Even this year, when FDA granted an application from manufacturer NJOY for a menthol-flavored product, the Agency declined to articulate how it balances benefits and risks. FDA said the authorized products were, relatively speaking, substantially effective at helping smokers quit, but didn't say what the cut-off was. Nor did FDA explain how it was measuring risk to youth against the relative adult switching rates. *FDA Authorizes Marketing of Four*

Menthol-Flavored E-cigarette Products After Extensive Scientific Review (June 21, 2024), https://tinyurl.com/5n8vk58d.

Still today, FDA cannot tell applicants what the key statutory phrase means: "appropriate for the protection of the public health." Instead of explaining how the Agency was going to weigh risks and benefits, the Agency has shifted the meaning of the phrase unpredictably. All so that the Agency can bow to political pressure to "do something" about youth vaping. And the "something" FDA had in mind was to ban flavored e-cigarettes from the market. *See RJRV Vibe*, 65 F.4th at 193–94 (holding that FDA adopted a de facto ban on flavored e-cigarettes). But FDA's single-minded focus has led it to cut corners, rush the application deadline, commit unforced errors, and require courts (including this one) to hold the Agency to account.

6. Unsurprisingly, heat on FDA remains high—and for good reason. Applicants have launched dozens of challenges to FDA's denial orders. FDA has had to stay or rescind a number of denial orders. FDA, "Marketing Denial Orders," *Tobacco Products Marketing Orders* (listing denial orders and their statuses), https://tinyurl.com/mrx3zybb. In fact, FDA stayed and eventually rescinded the denial order for JUUL's products after the Agency realized it overlooked 6,000 pages of aerosol data containing the exact measurements FDA said were missing. *See* FDA, *Update on FDA's Scientific Review of JUUL Product Applications* (June 6, 2024), https://tinyurl.com/bd96cjyx; *see also* Stay Mot., *Juul Labs, Inc. v. FDA*, No. 22-1123 (D.C. Cir. June 23, 2022); Abeyance Mot., *id.* (June 30, 2022).

In addition, elected officials of both parties have condemned the Agency for its mishandling of e-cigarettes. For example, Senator Durbin stated that FDA "has one of the worst records in history of following through and ensuring compliance with enforcement." 169 Cong. Rec. S.4340–41 (Sept. 11, 2023).

Even more recently, "a group of nearly 70 House Republicans … pressed the president to move forward with long-pending applications for new smoke-free products to be approved by the FDA." Cami Mondeaux, *House Republicans press FDA to expedite approval process for smoke-free tobacco products*, Washington Examiner (Mar. 12, 2024).

* * *

FDA has been at sea for the better part of a decade, and left applicants floundering. FDA began its foray into regulating these products with no plan for an authorization pathway. As it continually failed to come up with one, the Agency repeatedly changed the application deadline, pushing it further and further until a court stepped in and drastically accelerated it. In addition to moving the temporal goalposts, FDA secretly moved the substantive and evidentiary goalposts. Where it once said no specific comparisons were required for flavored e-cigarettes, FDA now says flavored e-cigarettes must be compared to tobacco-flavored ones to show flavors outperform tobacco e-cigarettes when it comes to getting adult smokers to switch. Where it once said no specific evidence was required for flavored e-cigarettes, FDA now says long-term, product-specific studies on switching are required. Where it once said marketing plans were

critical for applications, FDA now says it ignored those plans. Where it once said menthol must be treated differently from other non-tobacco flavors, FDA now says all flavors are the same and subject to the same requirements. And where it once said that open systems were different from other types of e-cigarettes when it came to youth use, FDA now says all device types are the same and subject to the same requirements.

These regulatory pump fakes represent changes in position with no notice to the regulated parties; thus, they are all quintessential arbitrary and capricious agency action, as Respondents explain in their merits brief. *See, e.g.*, *Martin v. OSHRC*, 499 U.S. 144, 158 (1991) (lack of pre-enforcement warning raises questions about "the adequacy of notice to regulated parties").

Agencies often face political pressures. But "[r]egardless of how serious the problem an administrative agency seeks to address, ... it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000). Because FDA committed numerous, independent legal errors in this case, the judgment below should be affirmed.

II. MENTHOL E-CIGARETTES PRESENT DISTINCT PUBLIC-HEALTH ISSUES FROM THE OTHER-FLAVORED PRODUCTS AT ISSUE HERE.

Regardless how the Court resolves the denial orders about non-menthol flavored e-cigarettes at issue here, menthol is decidedly different. Indeed, in passing the TCA, Congress explicitly acknowledged that menthol

is unique among flavors. Congress specifically allowed menthol *cigarettes* to remain on the market even while banning all other characterizing flavors (save tobacco). 21 U.S.C. § 387g(a). And a smoker of menthol cigarettes looking for a less risky option would most naturally turn to menthol e-cigarettes. That is why, in part, FDA's expert science staff unanimously recommended that the Agency authorize menthol e-cigarettes as appropriate for the protection of the public health. But that uniform assessment was overruled by the new Director of the Center for Tobacco Products "[w]ithout citing any scientific studies or published articles." *Logic*, 84 F.4th at 559 (Porter, J., dissenting). There is no doubt that FDA's multiple about-faces on other flavored e-cigarettes were arbitrary and capricious. But FDA's "switcheroo" on menthol was even more egregious. As the Fifth Circuit and Judge Porter have explained, FDA's about-face on menthol is plainly arbitrary, even ignoring what FDA did with other flavors. *RJRV Vibe*, 65 F.4th at 190–91; *Logic*, 84 F.4th at 559 (Porter, J., dissenting). Because of this, even if this Court were to uphold FDA's orders in this case, it should make clear that menthol presents special considerations that are not at issue here.

A. Congress, FDA, and public-health experts treat menthol differently than other e-cigarette flavors.

Congress, FDA, and public-health experts have repeatedly recognized the unique public-health considerations—and even the distinctive potential public-health *benefits*—of menthol e-cigarettes. These factors require distinguishing challenges to denial orders involving menthol e-cigarettes from the

challenge here, which involves non-menthol-flavored products.

1. In the TCA, Congress prohibited characterizing flavors in cigarettes, but specifically carved out tobacco and menthol flavors from that ban. 21 U.S.C. § 387g(a)(1)(A). Whereas any "artificial or natural flavor … herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee" is prohibited as a characterizing flavor, "menthol" is not. *Id.* And Congress further directed FDA to promptly study menthol cigarettes by referring the question of their public-health effects to an expert committee. *See* 21 U.S.C. § 387g(e).

Congress enacted this carveout because it "recognize[d]" both "the unique issues surrounding menthol cigarettes" and "that menthol cigarettes may pose unique health risks to those who smoke them." H.R. Rep. No. 111-58, pt. 1, at 38 (2009) ("TCA House Report"). Accordingly, Congress "believe[d]" that it was "critical for the Secretary to move quickly to address the unique public health issues posed by menthol cigarettes." *Id.* at 38–39. As one of the TCA's sponsors repeatedly emphasized, "menthol cigarettes will be an early focus of the agency's attention." 155 Cong. Rec. H4318-02, at 4339 (daily ed. Apr. 1, 2009) (statement of Rep. Waxman); *see* 155 Cong. Rec. H6630-01, at 6652 (daily ed. June 12, 2009) (statement of Rep. Waxman).

Congress's decision not to ban menthol cigarettes flowed from its decision to instead target "'characterizing flavors' that appeal to youth"—a decision it viewed as "[c]onsistent with the overall

intent of the bill to protect the public health, including by reducing the number of children and adolescents who smoke cigarettes." TCA House Report at 37. It "concluded that the ban [on all flavors except menthol and tobacco] will not lead to negative public health effects, because of how the affected products generally are used and because of their low overall use by adult smokers." *Id.* at 38. Banning menthol, on the other hand, "would pose different questions of public health." *Id.* (citing potential increases in "demand for cessation assistance" and "the illegal black market risk, which could also pose a health hazard to users").

2. Similar considerations apply to menthol e-cigarettes. Indeed, FDA has repeatedly recognized differences in the respective public-health impacts of menthol e-cigarettes and other-flavored e-cigarettes. These differences are also demonstrated by the scientific literature.

In FDA's own words, "[m]enthol is unique compared to other available [e-cigarette] product flavors as it is the only characterizing flavor available in cigarettes." J.A. 170 (*Enforcement Priorities*). For this reason, it is important for menthol e-cigarettes to remain available as potentially reduced-risk alternatives for menthol smokers, as FDA recognized when it exempted menthol-flavored products from its 2020 decision to prioritize enforcement against flavored cartridge-based e-cigarettes, *see id.*, and again during its initial consideration of e-cigarette applications, *see, e.g.,* J.A. 234a n.ii (FDA, Technical Project Lead for Wages & White Lion (Sept. 9, 2021)) ("When it comes to evaluating the risks and benefits of a marketing authorization, the assessment for menthol [e-cigarettes], as compared to other non-

tobacco- flavored [e-cigarettes], raises unique considerations."). In addition to having unique benefits for adult smokers, menthol e-cigarettes pose less risk to youth than the other non-tobacco-flavored products at issue in this case: Even in this Court, FDA acknowledges that "youth use of menthol products is greater than tobacco flavor, but lower than other flavors such as candy, desserts, and sweets." FDA Br. 49.

In keeping with Congress's direction to study and consider whether to issue a tobacco product standard regarding menthol as a characterizing flavor in cigarettes, FDA not once but twice declined to issue such a standard after receiving myriad comments about such a policy's public-health effects. *Regulation of Flavors in Tobacco Products*, 83 Fed. Reg. 12,294, 12,299 (Mar. 21, 2018); *Menthol in Cigarettes, Tobacco Products*, 78 Fed. Reg. 44,484 (July 24, 2013). And FDA has paused its third and latest attempt to confront the issue, again suggesting that menthol's unique public-health considerations differ from other flavors that Congress and FDA have chosen to ban. *See* WSJ, *Biden Administration Shelves Plan to Ban Menthol Cigarettes* (Apr. 26, 2024), https://tinyurl.com/yw9zn6ny; *see also Tobacco Product Standard for Menthol in Cigarettes*, 87 Fed. Reg. 26,454 (May 4, 2022).

For now, menthol-flavored cigarettes remain on the market, so—again, in FDA's own words—"menthol-flavored [e-cigarettes] could be a direct substitute for them, providing a less harmful alternative for menthol-flavored cigarette smokers." FDA, Memo., *Development of the Approach to Evaluating Menthol-Flavored ENDS PMTAs* (Oct. 25, 2022),

https://tinyurl.com/ysn6njtz. And those potential benefits for "menthol cigarette smokers" and "dual users of menthol cigarettes and [e-cigarettes]" require a different appropriate-for-the-protection-of-the-public-health analysis than the candy- and dessert-flavored e-cigarettes at issue here. 87 Fed. Reg. at 26,479 (citing "surveys," "[e]xperimental marketplace studies," "the 2020 Surgeon General's Report, titled 'Smoking Cessation,' and several systematic reviews"). Moreover, if FDA *does* ban menthol cigarettes, it will be even more important for menthol e-cigarettes to be available as an alternative for menthol smokers who might otherwise turn to tobacco-flavored cigarettes or illicit-market menthol cigarettes.[5]

Although FDA changed its tune at the direction of a new appointee in 2022, as discussed further below, current data confirm FDA's original position on menthol e-cigarettes. The 2024 National Youth Tobacco Survey shows that menthol's popularity among youth has steadily and significantly declined in recent years: in 2022, 26.6% of surveyed youth who regularly used e-cigarettes reported using menthol-flavored e-cigarettes; in 2024, that number has

[5] Studies conducted by NJOY LLC in support of several applications that FDA recently granted for its menthol-flavored e-cigarettes also show that current smokers are more likely to be drawn to menthol e-cigarettes than to tobacco-flavored ones. FDA, NJOY ACE Decision Summary 7–8 (June 21, 2024) (discussing "robust and reliable evidence that the menthol-flavored [e-cigarette] is associated with significant and substantially higher rates of complete switching than tobacco-flavored [e-cigarettes]"), https://tinyurl.com/5n8vk58d; FDA, NJOY DAILY Decision Summary 8–9 (June 21, 2024) (same), https://tinyurl.com/5n8vk58d.

dropped to 15.1% (as compared to 62.8% reporting using fruit flavors and 33.3% reporting using flavors mimicking candy, desserts, or other sweets). CDC, *Notes from the Field* (Sept. 5, 2024), https://tinyurl.com/dkj2spja; CDC, *More than 2.5 Million Youth Reported E-cigarette Use in 2022* (Oct. 6, 2022), https://tinyurl.com/msf98n8r.[6]

The overwhelming weight of scientific evidence—as recognized by Congress, FDA (both before and after its about-face), and public-health experts—has consistently distinguished the public-health effects of menthol-flavored products from those of the other-flavored products here.

B. FDA's "switcheroo" on menthol was more egregious.

FDA's flip-flop on menthol e-cigarettes presents an even worse switcheroo than the one Respondents challenge here. As discussed above, Congress and FDA repeatedly acknowledged that menthol is unique. Moreover, FDA scientists unanimously recommended authorizing menthol e-cigarettes as appropriate for the protection of the public health. *Logic*, 84 F.4th at 559 (Porter, J., dissenting) (discussing "the unanimous [Office of Science] divisions' careful scientific analyses"). Indeed, "every discipline within the [FDA

[6] Moreover, when it comes to menthol e-cigarettes, FDA makes no distinction between the types of products RJRV manufactures—cartridge-based e-cigarettes—and cheap disposable e-cigarettes. This even though disposables are nearly four times more popular than cartridge-based e-cigarettes with youth who use e-cigarettes. *See* Jan Birdsey, et al., *Tobacco Product Use Among U.S. Middle and High School Students—National Youth Tobacco Survey, 2023*, 72 MMWR 1173 (Nov. 2023).

Office of Science] concluded that [the] menthol products should be approved." *Id.* at 558. That conclusion is hardly surprising given that menthol is the only characterizing flavor allowed in cigarettes (other than tobacco). Obviously, a menthol smoker looking for a potentially less risky alternative would prefer a menthol e-cigarette over a tobacco-flavored one.

As Judge Porter has explained, there was no disagreement among FDA's scientists about menthol e-cigarettes. *Id.* FDA's Social Science department noted that the "menthol flavored new products ... have lower youth appeal," and "may offer menthol cigarette smokers an appealing option to transition away from combusted cigarette smoking, an option particularly important given some menthol smokers' lower rates of combusted cigarette cessation." *Id.* at 559. Epidemiology also distinguished menthol from other flavored e-cigarettes. *Id.* The other disciplines—Engineering, Chemistry, Microbiology, Behavioral and Clinical Pharmacology, and Medical—all concurred that menthol e-cigarettes should be authorized. *Id.*

Based on input from all of the disciplines, the overall conclusion of the Office of Science was that menthol e-cigarettes should be authorized. The Office found that the "'potential benefit' of adult menthol smokers switching from combustible cigarettes to menthol [e-cigarettes] 'amounted to a likelihood of greater cessation or significant reduction in smoking that would outweigh the known risks to youth from the marketing of the products, sufficient to meet the legal standard for authorization.'" *Id.*

Moreover, FDA affirmatively told applicants that menthol e-cigarettes would *not* be treated like other flavors. For example, while RJRV's applications were pending, FDA sent the company a "deficiency letter" that said comparative-efficacy studies would not be required for menthol e-cigarettes. Specifically, the "deficiency letter regarding several other pending [applications] for RJRV's flavored [e-cigarettes]," "instructed RJRV to 'provide evidence to demonstrate that the use of these flavored products (*other than menthol*) increases the likelihood of complete switching among adult smokers relative to tobacco or menthol-flavored products.'" *RJRV Vibe*, 65 F.4th at 188 (quoting deficiency letter). In other words, such evidence was *not* required for menthol e-cigarettes.

But then, unbeknownst to anyone outside the Agency, FDA changed its tune regarding menthol-flavored e-cigarettes at the direction of a new appointee in 2022, and "[w]ithout citing any scientific studies or published articles." *Logic*, 84 F.4th at 559 (Porter, J., dissenting); *see RJRV Vibe*, 65 F.4th at 192 ("a new CTP director appeared … and told [the Office] that … 'the products could be [authorized] only if the evidence showed that the benefits of the menthol-flavored [e-cigarette] were greater than tobacco-flavored [e-cigarette]'"). The Director's *ipse dixit* edict was "that 'scientific evidence on the role of flavors in youth use of [e-cigarettes] is significantly more rigorous and robust than the preference data concerning menthol combustible cigarette smokers.' Therefore, 'robust evidence of benefit is required to overcome the risk to youth and show that authorizing the marketing of a menthol-flavored [e-cigarette] would be appropriate for the protection of the public

health.'" *Logic*, 84 F.4th at 559 (Porter, J., dissenting) (internal citations omitted). In other words, unlike FDA's prior directives—making clear that menthol would *not* be treated like other flavors—FDA *sub silentio* reversed course. "Chastened by the new directive, [the Office of Science] leadership acquiesced to [the Director's] policy decision 'to treat menthol-flavored [e-cigarette applications] in the same way as other non-tobacco-flavored [e-cigarette applications] regarding the evidence needed to show a potential benefit to adult smokers.'" *Id.*

That policy then became the basis for a raft of denials for menthol e-cigarettes. *See RJRV Vibe*, 64 F.4th at 193. Some manufacturers, like RJRV, tried to give FDA exactly what it was now requiring. RJRV commissioned a study on how effective its menthol e-cigarettes are in helping adult smokers switch. The results were promising. They showed that at twelve months, adult smokers switched to menthol Vuse products at a higher rate (42%) compared to tobacco-flavored Vuse products (37.2%) and that users of menthol Vuse products saw a greater decrease in cigarettes per day (-5.5) compared to users of tobacco-flavored Vuse products. (-2.7). *See* Stay App'x A22, *RJRV v. FDA*, No. 23-60545 (5th Cir. Oct. 20, 2023). And FDA was well aware of this study. *See id.* In fact, in October 2023, RJRV, on its own accord, sent the study's results to FDA while RJRV's application for Vuse Alto was pending. *Id.* Nonetheless, after sitting on RJRV's application for over two years, FDA denied it *the day after the data was sent*, without even reviewing the new data that FDA has since announced it was requiring, and without requesting such data

through a deficiency letter (as FDA had done for other applications).

It is thus quite clear that FDA's decisions—contrary to its claims—are not driven by science. Indeed, an independent foundation evaluated FDA's handling of e-cigarettes and concluded that "a lack of clarity about the distinction between, and the intersection between, policy and science has created controversy within [FDA's Center for Tobacco Products] and may lead to a perception that the Center's scientific integrity is being challenged when, in fact, policy decisions that transcended the science are being made." *See* Lauren Silvis et al., *Operational Evaluation of Certain Components of FDA's Tobacco Program*, Reagan-Udall Found. 15 (2022), https://perma.cc/NP3A-3QNJ. As FDA staffers have confirmed, "scientific decisions" are being "overruled by political agendas and [staffers are being] pushed to change decisions."[7]

Because FDA's new standard for menthol e-cigarettes was a policy change, FDA was required to "supply a reasoned analysis." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57 (1983); *see also CBS Corp. v. FCC*, 663 F.3d 122, 138 (3d Cir. 2008). But FDA has never offered a reasoned explanation—instead relying on its new Director's policy preferences. Indeed, FDA has not even acknowledged "that it *is* changing position." *See FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515 (2009). An agency "fail[ing] to acknowledge that it has changed its policy ... is unable to comply with the requirement under *State Farm* that an agency supply

[7] Allison Boughner, *FDA Stakeholders Break Their Silence*, World Vapers' Alliance (Nov. 15, 2022).

a reasoned explanation for its departure from prior policy." *CBS Corp.*, 663 F.3d at 151–52.

Accordingly, FDA's denial orders for menthol e-cigarettes represent an even more egregious and indefensible "sudden turnabout" than the turnabouts on other flavors. *See RJRV Vibe*, 65 F.4th at 192.

C. Even if the Court upholds the denials at issue here, it should make clear that menthol-flavored products, which are not at issue, are different.

Menthol is clearly different from other e-cigarette flavors, and this Court's decision should reflect that reality.

To summarize, Congress, FDA, and public-health experts have long recognized the fundamental differences between menthol and other flavors; FDA's Office of Science unanimously concluded that menthol e-cigarettes should be authorized; and FDA's deficiency letter to RJRV expressly distinguished menthol-flavored e-cigarettes from those with other flavors. *See supra* Part II.A–B. Yet, at the whim of a new Director of the Center for Tobacco Products, the Agency changed course, ignoring its past position on menthol, the science, and even applicants' studies that satisfy FDA's newly minted standard.

It is true that if this Court concludes that FDA's switcheroo on *non*-menthol flavors was arbitrary and capricious, then, *a fortiori*, FDA's switcheroo on menthol was too. *See RJRV Vibe*, 65 F.4th at 192. But the reverse is not true, because challenges to FDA's denial orders for menthol-flavored e-cigarettes raise different (even more serious) merits questions. In other words, even beyond product-specific and

application-specific questions about the reasonableness of each individual denial, menthol-flavored e-cigarettes as a category present different public-health considerations that, according to FDA's own scientists, mean they are "appropriate for the protection of the public health" even if other flavors are not.

Therefore, even if this Court were to uphold FDA's actions for *non-menthol* flavors (it should not), FDA's actions on *menthol* were clearly arbitrary. Its "switcheroo" on menthol, especially considering everything the Agency had said before (and in deficiency letters to applicants), was even more egregious than with other flavors. *RJRV Vibe*, 65 F.4th at 187 (noting differences between applications for menthol products and other flavors, including FDA's deficiency letter clarifying that menthol would be treated like tobacco-flavored products).

Because of these fundamental differences, the Court should scrupulously avoid opining on FDA's treatment of menthol-flavored e-cigarettes. As Judge Porter recognized, rulings on other-flavored e-cigarettes do not control the disposition of cases involving menthol-flavored e-cigarettes. *Logic*, 84 F.4th at 565 n.3 (Porter, J., dissenting) ("Unlike this case and *R.J. Reynolds*, our decision in *Liquid Labs* addressed only fruit-and-dessert flavored [e-cigarettes] and not menthol-flavored or tobacco-flavored [e-cigarettes]."). Cases involving menthol, he explained, turn on "FDA's decision to treat menthol products like fruit, dessert, and candy [e-cigarettes] despite previously treating menthol like tobacco given its lower youth appeal and benefit as a combustible cigarette alternative for adult smokers." *Id.* Judge

Jones's opinion for the Fifth Circuit similarly recognized that FDA's (i) deficiency letter to RJRV specifically carving out "menthol" products and (ii) "prior statements about the low popularity of menthol-flavored e-cigarettes among youth and substantial benefits for cigarette smokers who make the switch" both exacerbated the arbitrariness of how FDA handled *Amici*'s applications. 65 F.4th at 188, 192.

FDA would be hard-pressed to maintain its denial orders for menthol-flavored e-cigarettes if this Court rules in favor of Respondents. But if this Court rules in favor of the Agency, the Court should make clear that it is *not* resolving the different merits and public-health questions presented by menthol products.

CONCLUSION

The judgment below should be affirmed.

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