No. _____

In the Supreme Court of the United States

VDX DISTRO, INCORPORATED;
VAPETASTIC, L.L.C.,

Petitioners,

v.

UNITED STATES FOOD & DRUG ADMINISTRATION;
KYLE DIAMANTAS, ACTING COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
ROBERT F. KENNEDY, JR., SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Family Smoking Prevention and Tobacco Control Act (TCA) authorizes the Food and Drug Administration (FDA) to adopt "tobacco product standards" which govern the "construction, components, ingredients, additives, constituents, ... and properties" of tobacco products. 21 U.S.C. §§ 387g(a)(3)–(4). The TCA requires APA notice-and-comment rulemaking. *ID.* at § 387g(c). FDA must deny a premarket tobacco product application (PMTA) for products that do not conform to these standards unless there is "adequate information to justify the deviation" therefrom. *Id.* § 387j(c)(2)(D).

Without rulemaking, FDA has required every non-tobacco-flavored product to statistically outperform a tobacco-flavored product in converting smokers. The court below held this requirement is not a product standard, but "a balancing test, not a ban."

Separately, regulating tobacco is a major question. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000). The TCA immediately subjected four cigarette-related product categories to FDA regulation but left it to decide which "other tobacco products" to regulate through a regulatory deeming. 21 U.S.C. § 387a(b). The questions presented are:

1. Whether FDA's uniform condition on the marketing of every non-tobacco-flavored vaping product—enforcement of a flavor-triggered comparative efficacy requirement—is a "tobacco product standard" for which the TCA § 387j required notice-and-comment

rulemaking. This question parallels the one this Court left open in *FDA v. Wages and White Lion Investments, L.L.C.*, 604 U.S. 542, 565 (2025).

2. Whether § 387a(b)'s "deeming" provision is unconstitutional because Article I, enforced through the major questions doctrine, required Congress to specifically decide which "other tobacco products" to regulate.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Petitioners VDX Distro, Incorporated (VDX) and Vapetastic, L.L.C. (Vapetastic) were the petitioners in the court of appeals.

Respondents United States Food & Drug Administration; Kyle Diamantas, in his official capacity as Acting FDA Commissioner; the United States Department of Health and Human Services (HHS); and Robert F. Kennedy, Jr., in his official capacity as HHS Secretary, were collectively the respondents in the court of appeals.

Pursuant to this SUP. CT. R. 29.6, neither VDX nor Vapetastic have a parent corporation and no publicly held corporation owns 10% or more of their stock or membership interests.

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Petitioners, VDX and Vapetastic, respectfully petition for a writ of certiorari to review the June 24, 2026 opinion and judgment entered thereon by the United States Court of Appeals for the Fifth Circuit.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a–24a) is reported at 179 F.4th 356 (5th Cir. 2026). The order denying panel rehearing and rehearing *en banc* (App. 27a-28a) entered on August 21, 2026 is unreported. The order of the FDA denying VDX's PMTA in Agency No. PM0002351 is unreported but recited in pertinent part at App. 38a-43a.

JURISDICTION

The court of appeals entered judgment on June 24, 2026, app. 25a-26a, following its August 21, 2026 denial of timely petitions for panel rehearing and rehearing *en banc*, app. 27a-28a. This Court has jurisdiction under 28 U.S.C. § 1254(1). This Petition is timely becauseVDX and Vapetastic bring it within 90-days of the Fifth Circuit's August 21, 2026 order denying rehearing. SUP. CT. R. 13.1, 13.3

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article I, § 1 of the United States Constitution provides: "All legislative Powers herein granted shall be vested in a Congress of the United States . . . ."

Relevant provisions of the TCA[1] are reproduced at App. 44a–55a.

STATEMENT OF THE CASE

This case presents the question this Court expressly reserved in *Wages*: whether FDA may impose uniform, flavor-based market-access standards through informal adjudications rather than notice-and-comment rulemaking. 604 U.S. at 549. The court below found FDA's review process for non-tobacco flavored vaping products was not a TCA tobacco product standard and deferred to its informal PMTA adjudication authority. App. 17a–18a. At issue is whether the TCA required FDA to adopt those standards through public notice-and-comment rulemaking.

FDA's implementation of the TCA has given rise to an array of foundational Administrative Procedure Act (APA)[2] challenges.[3] This Court

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[1] Family Smoking Prevention and Tobacco Control Act, PUB. L. 111–31, 123 STAT. 1776 (Jun. 22, 2009), codified as 21 U.S.C. §§ 387 *et seq.*

[2] Administrative Procedure Act, PUB. L. 79-404, 60 STAT. 237, codified as 5 U.S.C., §§ 500, *et. seq*., (Jun. 11, 1946).

[3] This Court has heretofore adjudicated two APA-centric cases with multiple other cases being filed in 10 federal circuits. APA vacatur eliminated FDA's ability to impose civil monetary penalties absent Article III jury trials, *Texas Tobacco Barn, LLC. v. HHS*, 180 F.4th 229 (5th Cir. 2026), or impose the same heightened standard triggered by a product's flavor, *NicQuid, L.L.C. v. FDA,* 188 F.4th 190 (5th Cir. 2026). APA vacatur has also limited FDA's

addressed elements thereof in both *Wages* and *FDA v. R.J. Reynolds Vapor Co. (RJVC)*, 606 U.S. 226 (2025).

Petitioners also present a second, structural question—the precision Congress must use when constructing the TCA's "*if, what and when*" legislative prongs. This second question arises from *Brown & Williamson's* major question finding. Petitioners focus on three inquiries of the legislative process: *if to regulate, what to regulate, and when to regulate*. The TCA's deeming provision left these core legislative policy inquiries to FDA for the vast mosaic of "other tobacco products." Petitioners present the question whether Article I of the United States Constitution required Congress to specifically determine the "*if, what and when*" questions *vis-à-vis* tobacco products.

A. STATUTORY BACKGROUND

The TCA gave FDA immediate authority to regulate "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco."[4] TCA § 387a(b). The same provision deferred to FDA to "deem" the vast mosaic of "other tobacco products" subject to the TCA. *IBID.* In 2016, FDA issued a rule which fully exercised such deeming authority. 81 FED. REG. 28,914 (May 10, 2016).

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ability to regulate cigarette warning labels. *R.J. Reynolds Tobacco Co. (RJRT) v. FDA,* 189 F.4th 189 (5th Cir. 2026).

[4] Defined respectively at 21 U.S.C. § 387(3), (4), (15), and (18).

The TCA also empowers FDA to promulgate "tobacco product standards" through notice-and-comment rulemaking. TCA §§ 387g(a)(3), g(c). The TCA commands FDA to "deny" any PMTA which does not conform to applicable tobacco product standards. *ID.* § 387j(c)(2)(D).

Separately, the TCA directs FDA to "deny" a PMTA unless covered products are "appropriate for the protection of the public health" (APPH). TCA § 387j(c)(2)(A). This metric considers "the risks and benefits to the population as a whole." *ID.* at § 387j(c)(4). This adjudicatory pathway carries no rulemaking obligation.

This case and the Fifth Circuit's recent ruling in *NicQuid, supra*, intersect these pathways. Product standards draw categorical lines for classes of products based upon formal rulemaking. The panel below countenanced FDA universally applying a flavor-based standard when making APPH determinations for PMTAs in informal case-specific adjudications under *SEC v. Chenery Corp. (Chenery II)*, 332 U.S. 194 (1947).

NicQuid went the other way in finding FDA's standard was an APA rule which lacked required rulemaking. *NicQuid* accords with *Wages's* finding that FDA applied a heightened evidentiary standard—its "comparative efficacy" standard—for non-tobacco flavored vaping products. *Compare NicQuid, slip op*. at 18 to *Wages*, 604 U.S. at 578.

B. FDA'S COMPARATIVE-EFFICACY STANDARD

It is undisputed that FDA adopted its comparative standard without resort to notice-

and-comment rulemaking. *Wages* framed the standard—PMTAs must show that flavored products:

> "promote more switching" or substantially reduce smoking more than "tobacco-flavored e-cigarettes,"

and FDA will "categorically reject" applications absent that "precise comparison." *Wages*, 604 U.S. at 578, 580.

FDA uniformly applies the standard to every non-tobacco-flavored product PMTAs. FDA issues marketing denials, as it did here, every time products cannot make the required cross-flavor statistical comparison. FDA also applies an irrebutable presumption not overcome by other evidence that marketing the product would, on balance, protect the public health. In practice, the standard has produced the denial of well over a million PMTAs for flavored vaping products.[5] *See Wages*, 604 U.S. at 550.

C. VDX'S PMTA AND THE DECISIONS BELOW

VDX sells menthol and menthol-tobacco-flavored e-liquids, sold under the "Four Seasons" brand, for use in open-system vaping devices. App. 30a-32a. VDX has adopted professional and adult-

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[5] TCA § 387j(c)(1)(A) mandates that FDA adjudicate accepted PMTAs within 180 days of "receipt." Manufacturers are presently challenging FDA's systemic failure to satisfy its statutory review mandate. *See Helix Innovations, LLC v. FDA*, No. 5:26-cv-00199-H (N.D. Tx, filed Sept. 2, 2026).

oriented trade dress for such products[6] which it sells exclusively through age-restricted retail channels. *ID.* at 32a. No Four Seasons product has ever been documented as the subject of an underage-sale violation according to FDA's retail market compliance database. *ID.*

VDX timely filed its PMTA in September 2020; which FDA accepted in December 2020. FDA did not adjudicate VDX's PMTA for the Four Seasons products until September 2024, long after the TCA's 180-day statutory review deadline. VDX included its adult-oriented marketing plan which targets consumers aged 35 and older and restricts sales through age-gated retailers. App. 33a. FDA nonetheless uniformly applied its comparative standard to deny VDX's PMTA. It also brushed aside VDX's marketing plan elements—presuming judicial deference to its irrebutable presumption that such plan elements were ineffective at curbing youth access irrespective of whether such elements worked as to its products.[7] App. 40a.

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[6] https://fourseasonseliquid.com/original/

[7] FDA premised its PMTA reviews upon the proposition that:

> "only the most stringent mitigation measures have such potential; to date, the only such measures identified with the potential for that kind of impact have been device access restrictions. FDA is currently aware of no other restrictions with the potential to alter the overall net benefit assessment for flavored ENDS."

A Fifth Circuit panel denied the Petitioners' petition for review, holding that FDA's comparative standard was not a "tobacco product standard." The panel instead characterized the standard as a mere "methodology developed to apply the TCA's APPH standard"—"a balancing test, not a ban." App. 12a, 15a-16a. The panel further held Petitioners' major questions doctrine challenge was substantively a nondelegation argument "foreclosed" by *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436 (5th Cir. 2020). App. 11a. The court of appeals denied panel rehearing and rehearing *en banc*. App. 27a-28a.

REASONS FOR GRANTING THE PETITION

Wages "declined to reach" the antecedent and recurring question: whether FDA can adopt its comparative-efficacy standard through informal "adjudication rather than . . . notice-and-comment rulemaking." *Wages*, 604 U.S. at 549. That reserved question controls the outcome here.

A different Fifth Circuit panel in *NicQuid* has since held that FDA's comparative standard is an APA rule implemented without notice-and-

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FDA, Technical Project Lead Review of PMTAs at 5 (Sept. 19, 2024). https://www.dropbox.com/scl/fi/bvxkxagfh5w1aqtepjxlw/AR-180-219-Appx-125-164_.pdf?rlkey=h1dnqp4hvd2z1iub1pr664tpc&dl=0

FDA has since backed away from this premise. *See* Alex Kendall, *FDA Says Flavored Vapes Don't Need Built-In Age Verification,* Vaping 360 (Nov. 10, 2026).

comment rulemaking. *NicQuid*, *supra*, *slip op*. at 20–26. The panel below held the same standard is not a product standard subject to the TCA's own rulemaking requirement. FDA, meanwhile, has publicly confirmed that it uniformly applies the requirement to flavored vaping products, while declining to apply it at all to flavored nicotine pouches. The Court should grant review. Alternatively, the Court should hold this petition pending its disposition of any petition for a writ of certiorari in *NicQuid*.

This petition also presents a second, structural constitutional question. This Court's major questions doctrine jurisprudence looks to whether Congress articulated a "clear statement" granting the breadth of authority agencies claim over matters of national significance. This Court roots the doctrine in Article I principles. *West Virginia v. EPA*, 597 U.S. 697, 721–24 (2022).

Petitioners present a novel front-end Article I challenge to the precision Congress used when constructing the TCA's core questions: "*if to regulate*," "*what to regulate*" and "*when to regulate*." The panel below foreclosed the doctrine by immunizing Congress to vest agencies with authority to define core elements of public policy decisions—including determining the limits of their jurisdictional boundary over the subject of a major question.

I. THE PANEL IGNORED THAT FDA'S COMPARATIVE EFFICACY STANDARD SATISFIES THE ELEMENTS OF A TCA TOBACCO PRODUCT STANDARD.

FDA has never subjected its comparative standard to notice-and-comment rulemaking. The result has been serial litigation and a series of self-inflicted regulatory setbacks.[8] *See RJRT*, *NicQuid*; n. 3, *supra*.

Congress premised significant TCA inquiries upon its amorphous APPH metric. Congress applied the metric to product standards, § 387g(a); PMTA reviews, § 387j(c); reviewing modified risk products, § 387k(g).[9] FDA interpreted that metric to justify its universal imposition of a heightened evidentiary standard triggered by a product's flavor as a barrier to market authorization. *Wages*, 604 U.S. at 578. FDA uniformly denies market access absent a long-term study showing a product's efficacy statistically outperforms a comparator tobacco-flavored product. *IBID.* at 580. That is the context of this case—FDA premised its MDO upon such failure of proof. App. 39a-41a.

Congress created two pathways for FDA to adopt its comparative standard—both requiring APA rulemaking. The first, as *NicQuid* found, asks whether FDA implemented a substantive rule and

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[8] *Helix Innovations, supra*. demonstrate a series of self-inflicted regulatory challenges.

[9] Ironically, Congress did not predicate the most important FDA decision upon the APPH metric—its decision to invoke the TCA § 387a(b) deeming authority.

used notice-and-comment rulemaking to do so. *NicQuid, slip op*. at 20–26. The second asks whether FDA promulgated a "tobacco product standard" and whether it did so through notice-and-comment rulemaking. TCA rulemaking defaults to APA procedures. *See Perez v. Mortgage Bankers Ass'n*, 575 U.S. 592 (2015) (agency rulemaking defaults to the APA procedures).

A. APA RULEMAKING PATHWAY

NicQuid correctly found FDA's comparative standard was a substantive APA rule. A "rule" is "an agency statement of general or particular applicability *and future effect* designed to implement, interpret, or prescribe law or policy." APA § 551(4) (emphasis added). Substantive rules have the force and effect of law. *Chrysler Corp. v. Brown,* 441 U. S. 281, 295 (1979). *NicQuid* found FDA's standard satisfied that definition. *NicQuid*, *slip op*. 7-8. The requirement was binding on its face—applied as binding by FDA—and vacated in the absence of APA notice-and-comment rulemaking. *IBID.* at 23.

B. TCA RULEMAKING PATHWAY

TCA product standards require the same APA rulemaking. Congress authorized FDA's adoption of future[10] standards if they were APPH. TCA § 387g(a)(3). A standard impacts:

> "the reduction or elimination of an ***additive***, constituent (including a smoke constituent), or other

[10] Congress articulated the cardinal standard when banning characterizing flavors other than tobacco and menthol in cigarettes. TCA § 387g(a)(1).

> component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful…."

§ 387g(a)(3)(B)(ii) (emphasis added). Congress broadly defined the term "additive" to include:

> "any substance . . . otherwise affecting the characteristic of any tobacco product (***including any substances intended for use as a flavoring***….)"

ID. at § 387(1) (emphasis added).

The plain language of these coordinate definitions show FDA's comparative standard is a product standard in every way but name. It rests upon the presence of a non-tobacco characterizing flavor to trigger a heightened evidentiary burden as a predicate to market access.

Here, FDA has premised the development, implementation and application of this standard upon a presumption that youths prefer non-tobacco flavored vaping products. It imposes that universal standard to address a "provision" of a tobacco product—its flavor—to condition marketability.[11]

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[11] The standard is also a "testing" requirement under TCA § 387g(a)(4)(B)(ii)–(v). The standard touches upon: (1) product "testing;" (2) "measur[ing]" product characteristics; and (3) conditioning the "sale and distribution" of flavored vaping products.

The best statutory reading is that product standards exist when FDA premises marketability upon the inclusion of a non-tobacco flavor as an "additive." That is a product standard under the TCA's plain text—text which commands FDA to promulgate such standard through APA-type rulemaking. TCA §§ 387g(c)–(d). It is undisputed, as it was in *NicQuid,* that FDA failed to engage in that process.

C. FDA'S HISTORIC REGULATION OF FLAVORS AS A TOBACCO PRODUCT STANDARD.

The panel below also ignored FDA's previous invocation of TCA § 387g to regulate the inclusion of characterizing flavors in tobacco products. The TCA's cardinal product standard banned "artificial or natural flavor (other than tobacco or menthol)." *ID.* at § 387g(a)(1)(A). That ban included a broad list of flavors: herbs, spices, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee. *ID.* Congress's precise construction of this cardinal standard evidence its intent that future attempts to ban the inclusion of characterizing flavors in tobacco products would be TCA § 387g product standard.

FDA's comparative standard was not its first foray into the resulting inclusion of flavors in tobacco products:

- **March 2018**: FDA sought to regulate flavors in all tobacco products;[12]

[12] 83 FED. REG. 12,294, -295 (Mar. 21, 2018).

- **May 2022**: FDA proposed to ban menthol flavoring in cigarettes as an additives, constituent, component and property of products; [13] and
- **May 2022**: FDA proposed a product standard banning characterizing flavors in cigars.[14]

In each instance, FDA invoked TCA § 387g when proposing flavor-triggered proposed standards. The context of FDA's collective practice confirms that standards triggered by the presence of a characterizing flavor are § 387g tobacco product standards.

The issue here is whether FDA's comparative standard—uniformly enforced through PMTA adjudications—is a "tobacco product standard" subject to APA rulemaking. The Petitioners endorse *NicQuid's* findings that FDA's standard is an APA rule lacking rulemaking compliance. They assert here, as below, that such requirement is also a § 387g product standard requiring adherence to the same rulemaking process.

D. THE FIFTH CIRCUIT'S ANALYSIS

The panel below held that formal rulemaking was not needed because FDA's comparative standard was merely a "methodology," "balancing test," and a "rubric" for its application of the APPH standard, and not a "ban." App. 12a, 15a-16a, 23a. That holding cannot be reconciled with *NicQuid's* finding the same standard was a ban from an APA

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[13] 87 FED. REG. 26,454, -461 (May 4, 2022).

[14] 87 FED. REG. 26,396 -397 (May 4, 2022).

perspective. The view of the panel below contradicts with *R.J. Reynolds Vapor* Co. *v. FDA* (*RJRV*),[15] *NicQuid*, and this Court's description in *Wages*. It also contradicts § 387g's plain text.

Whether FDA's uniform enforcement of a heightened evidentiary standards, triggered by flavor, outside the TCA's rulemaking process through informal PMTA adjudications, is a question of exceptional and recurring importance given the mass of litigation it has brought.[16]

E. A TOBACCO PRODUCT STANDARD NEED NOT BE A BAN.

The panel's central premise—that a tobacco product standard must be a ban, and that FDA's comparative standard is "a balancing test, not a ban," App. 15a-16a—cannot be squared with the TCA's plain text, with the standards Congress itself enacted, or with FDA's own account of the requirement.

First, the TCA itself contemplates that products may deviate from a product standard. FDA must deny a PMTA when the product "is not shown to conform in all respects to a tobacco product standard in effect under section 387g . . . , *and* there is a lack of adequate information to justify the deviation from such standard." TCA § 387j(c)(2)(D) (emphasis added). Applicants may therefore obtain authorization for nonconforming products by supplying adequate information to

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[15] *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182 (5th Cir. 2023).

[16] *See* n. 3, *supra*.

"justify the deviation." A standard that yields to sufficient evidence is, by definition, not an outright ban. Section 387j(c)(2)(D) thus answers the panel's "balancing test, not a ban" reasoning directly: Congress designed product standards to operate as evidence-sensitive conditions on market access—exactly how FDA's comparative standard operates.

Nor does the standard's origin as a function of a public-health balancing distinguishes it from a product standard. The TCA directs FDA to adopt every product standard through the same weighing of "the risks and benefits to the population as a whole, including users and nonusers of tobacco products," that governs PMTA review. *Compare* TCA § 387g(a)(3)(B)(i), *with* § 387j(c)(4). Every product standard is the result of a balancing test.

Second, the TCA's pesticide-residue standard is a conditional limit, not a ban. It does not prohibit tobacco that contains pesticide residue; it bars it only if residue exceeds "any tolerance applicable under Federal law to domestically grown tobacco." TCA § 387g(a)(1)(B). The panel described that standard as setting "an upper limit on how much pesticide residue is allowed in tobacco products." App. 13a. Tobacco that meets the condition may be used; tobacco that does not, may not. FDA's comparative standard has the same functional structure. Non-tobacco-flavored products may be marketed only if they clear a flavor-triggered threshold—a "precise comparison" showing they outperform tobacco-flavored products. *Wages*, 604 U.S. at 580. If Congress's conditional pesticide residue limit is a product standard, so too is FDA's conditional limit on flavors.

Third, FDA's recent statements confirm the general applicability of its standard rather than case-by-case judgments. In March 2026 draft guidance, FDA stated that non-tobacco flavored products would "need to show that its product provides an added benefit compared to tobacco-flavored ENDS."[17] FDA's guidance described "the approach" as one "that the FDA has long applied in reviewing PMTAs for flavored ENDS products"; declaring the approach "remains unchanged."[18] FDA officials said the same at the agency's February 10, 2026 roundtable, where the session moderator explained that "the comparison versus tobacco flavors are things that need to be taken up in adult benefit."[19]

A requirement that an agency announces in advance, applies to every application in a product class, and describes as its settled approach is a rule of general applicability—not the residue of an individualized adjudication. And FDA's choice to restate it in guidance that, by its own account, is

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[17] FDA, *Draft Guidance for Industry: Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications—Considerations Related to Youth Risk* at 4 (Mar. 2026); *see* 91 FED. REG. 11,980 (Mar. 11, 2026).

[18] *ID.* at 4, 12.

[19] FDA, Transcript, *Roundtable on Premarket Tobacco Product Application Submissions for Electronic Nicotine Delivery Systems Products* at 16 (Feb. 10, 2026). https://www.fda.gov/media/191920/download?attachment

"non-binding," FDA Draft Guidance at 3, only underscores that FDA has never adopted it through the rulemaking § 387g(c) requires.

FDA's disparate treatment of nicotine pouches removes any doubt. In January 2025, FDA authorized twenty flavored *ZYN* branded nicotine-pouch products, including citrus, coffee, cinnamon, and several mint varieties, without requiring any showing that those flavors outperform a tobacco-flavored pouch. Its review instead treated flavor appeal as a youth-risk consideration "partially alleviated by the low overall nicotine pouch use rates by youth."[20]

Nicotine pouches and vaping products are subject to the same TCA statutory APPH standard. TCA § 387j(c)(2)(A), (c)(4). If FDA's comparative requirement truly "flows from the TCA itself," App. 17a, it would govern both. That FDA applies it to flavored vaping products but not to flavored nicotine pouches confirms that the requirement is an agency policy choice drawing a categorical, flavor-based line for one class of products—precisely what § 387g calls a product standard, and precisely what Congress required FDA to adopt through notice-and-comment rulemaking.

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[20] FDA, *Technical Project Lead (TPL) Review of PMTAs PM0000593–PM0000612*, at 32 (Jan. 13, 2025).https://www.accessdata.fda.gov/static/searchtobacco/ZYN/PMTA_TPL_PM593-PM612_Zyn_01_13_2025_Redacted.pdf

F. THE PANEL'S HOLDING CONFLICTS WITH *NICQUID* AND *WAGES*.

In *RJRV*, the Fifth Circuit granted a stay upon finding that FDA had likely violated the APA's rulemaking requirement because its "rigid" comparative-efficacy requirement on non-tobacco-flavored vaping products was a "new standard of evidence" and a *de facto* substantive rule whose procedural invalidity was "not a close call." *RJRV*, 65 F.4th 182, 192–94 (5th Cir. 2023). *NicQuid* confirmed that status. *NicQuid, slip op*. at 25.

The *NicQuid* panel reached the opposite answer to the same question found by the panel below. It is a logical disconnect that the same FDA gatekeeping requirement concerns a common subject matter and regulatory regime and is a ban under one matrix but merely a "methodology," "balancing test" or a "rubric" under another. Regulated parties now confront two opposing legal answers from the same court to the same practical question involving the same regulatory action and the same regulatory regime. That asymmetry and inconsistency is untenable.

The panel's characterization also collides with *Wages's* account of the standard. The panel below called the standard a "pliable threshold." App. 15a. That defies *Wages's* finding of FDA's "categorical[] reject[ion]" of all PMTAs that fail the standard's "precise [statistical efficacy] comparison." 604 U.S. at 578, 580. Standard that categorically reject entire product classes absent one specified form of proof—acting as a market barrier—is not a case-by-case balancing act. That standard is, in the panel's own vocabulary, a "categorical limit" and a

"hard-and-fast line as to certain attributes of tobacco products." App. 13a-15a.

FDA's authorization of a handful of menthol or pod-based non-tobacco flavored products does not defeat the point.[21] Conditional standards are still standards. FDA's authorizations simply confirm it imposes a higher, flavor-triggered threshold on non-tobacco-flavored products. That is precisely the sort of across-the-board condition for which § 387g demands rulemaking.

G. *CHENERY II* DOES NOT LICENSE FDA TO EVADE RULEMAKING.

Dispositively applying *Chenery II* is also another point where the opinion below is askew from *NicQuid* and *Wages*. The panel below leaned on the principle that agencies may "generally develop regulatory standards through either adjudication or rulemaking." App. 17a, citing *Chenery II,* 332 U.S. at 202-03. That reliance ignored what *Wages* highlighted as *Chenery II's* decisive limitation: "if a statute requires rulemaking, the affected agency must comply." 604 U.S. at 565. *NicQuid* confirms that FDA cannot hide behind *Chenery II* to justify enforcing its comparative standard through informal adjudications in the face of the APA's rulemaking mandate. *NicQuid, slip op*. at 26.

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[21] *NicQuid* noted FDA's approval of only 0.000333% of non-tobacco flavored vaping products. *NicQuid, slip op*. at 17.

FDA's standard applied elements keyed to TCA § 387g definitions to regulate:

(1) "the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product,"

(2) product testing;

(3) measuring product characteristics; and

(4) testing results conforming to product standards.

TCA § 387g(a)(4)(B)(i)-(iv). This standard satisfies the plain and unambiguous statutory elements for a § 387g(a).

However, FDA is not toothless. It may compare products when adjudicating particular vaping product PMTAs. It may not, however, say its application of a uniform, flavor-class rule is an informal individualized comparison. TCA § 387j(c) governs case-specific APPH determinations while § 387g governs generally applicable product standards in the context of APA § 551(4) and its requirements.

FDA crossed that line when making non-tobacco flavors trigger a uniform added-benefit burden. The requirement of APA rulemaking upon such triggering was not an empty formality. FDA has historically treated menthol distinct from candy, fruit, and dessert flavors. FDA has suggested that menthol vaping products are a closer substitute for menthol cigarettes. It later utilized an internal memorandum, not formal

rulemaking, to treat menthol like every other non-tobacco flavor.[22]

Notice-and-comment rulemaking would have allowed interested parties to put FDA to its proof—requiring it to justify the position reversal versus the effects on menthol smokers. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). That is exactly the type of vetting Congress prescribed in the APA. The panel's contrary approach lets FDA circumvent § 387g and the APA whenever it prefers adjudication, an outcome *Wages* and *Chenery II* do not permit.

II. ARTICLE I REQUIRES THAT CONGRESS CONSTRUCT THE CORE ELEMENTS OF STATUTORY REGIMES WHICH ADDRESS MAJOR QUESTIONS.

Article I, § 1 of the Constitution provides that "[a]ll legislative powers herein granted shall be vested in a Congress of the United States." This Court has developed two cousin interpretive doctrines: the major questions and nondelegation doctrines. Both evaluate the constitutionality of Congress delegating legislative authority.[23] Each

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[22] *See NicQuid, slip op*. at 8, 13.

[23] *See generally* Brian Chen & Samuel Estreicher, *The New Nondelegation*, 102 TEX. L. REV. 539 (2024) (examining the relationship between the two doctrines); Louis J. Capozzi III, *In Defense of the Major Questions Doctrine*, 100 NOTRE DAME L. REV. 509 (2025) (defending the doctrine as an appropriate implementation of Article I's limits on the delegation of legislative power).

address delegations in varying degrees. That is the end of their parallel. These doctrines are not the same functionally; each asks different questions and have different focuses.[24]

The nondelegation doctrine looks to whether Congress's proffered an "intelligible principle" guiding an agency's exercise of delegated power. *Whitman v. Am. Trucking Assn's*, 531 U.S. 457, 472 (2001). That inquiry is famously forgiving and this Court has invoked to invalidate only a handful of statutes. It has not done so at all since 1935. *See A.L.A. Schechter Poultry Corp. v. U.S.*, 295 U.S. 495 (1935), and *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). The doctrine's object is the *grant* of standardless power, not its exercise. Thus, a nondelegation challenge can succeed if an "intelligible principle" is absent even though an agency exercises perfect restraint.

The major questions doctrine operates on a different axis. The doctrine, to date, has asked whether Congress resolved a momentous policy choice through an open-ended delegation. The doctrine has looked for a "clear statement" authorizing the claimed agency power. *West Virginia*, 597 U.S. at 721–24. The Court has applied this inquiry as a back-end analysis when agencies claim the power to decide matters of vast

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[24] The separation of legislative and executive power is a structural guarantee of liberty, not a mere allocation of convenience. *See The Federalist No. 47*, at 301 (James Madison) (C. Rossiter ed., 1961) (accumulating legislative, executive, and judicial powers in the same hands may justly be pronounced the very definition of tyranny).

economic, historic, or political significance.[25] It is thus entirely possible to pass a nondelegation test and fail a major question one.

The ruling below demonstrates the possibility of passing a back-end analysis—showing a "clear statement"—while still violating Article I. This Court has yet to consider the major questions doctrine from a prospective which tests Congress's precision when constructing the core legislative policy elements of its regulatory regime. *If to regulate, what to regulate and when to regulate* are among these core elements. The panel below applied a back-end analysis to a front-end Article I question.

The express character of a delegation is not an answer to the Petitioners' premise of their Article I front-end challenge. Petitioners do not contend Congress hid an elephant in a mousehole, to borrow from *Whitman, supra.* 531 U.S. at 468. Instead, they contend that Congress handed FDA the elephant and then told FDA to both find its own shovel and dig its own holes. Congress handed FDA the elephant in explicit, but boundless, terms which gave it authority as to all aspects of the elephant's existence.

The authority to unilaterally decide *if* to regulate, *what* to regulate and *when* to regulate

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[25] The Framers understood that marking a boundary in theory does not secure it in practice, and that legislative power, in particular, tends to draw "all power into its impetuous vortex." *The Federalist No. 48*, at 309–10 (James Madison) (C. Rossiter ed., 1961); *see also id.* at 308 ("power is of an encroaching nature").

the diverse mosaic of "other tobacco products" to the TCA is the elephant which Congress gave FDA. That is a distinctively Article I-grounded major questions objection which the clarity of Congress's grant of authority cannot obscure. The clarity of Congress's statement when making a delegation begs if Article I barred it from handing FDA the "*if, what and when*" decisions.

A. THIS COURT'S PRECEDENT VERIFIES THE "BACK-END" CHARACTERIZATION

The Court's doctrinal precedent bears out the Petitioners' back-end characterization. *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014); *West Virginia, supra.* at 723; *Ala. Assn. of Realtors v. Dep't. of Health and Human Servs.*, 594 U.S. 758, 764 (2021) (*per curiam*); *NFIB v. OSHA*, 595 U.S. 109, 117 (2022) (*per curiam*) and *Biden v. Nebraska*, 600 U.S. 477, 501, 506 (2023) all focus on the "clear statement" inquiry. This precedent is distinct from a challenge to the precision Congress applied when crafting the core legislative policy elements of major questions. Here, Congress painted outside the lines more than Article I allows in TCA § 387a(b)'s deeming provision. Congress cannot defer the core "*if, what and when*" to regulate decisions when constructing the regulatory framework of a major question. That is a novel question before this Court.

B. THE MAJOR QUESTIONS DOCTRINE ADDRESSES STRUCTURAL ARTICLE I INQUIRIES.

The major questions doctrine is frequently described in narrow, procedural terms—a canon of construction withholding judicial deference from

agencies, or resolving statutory ambiguities against them, whenever they claim authority over a question of "vast economic and political significance." *See Util. Air Regul. Grp.*, *supra.* at 324.

That account is accurate as far as it goes, but it understates what the doctrine does and why it exists. At its foundation, the major questions doctrine enforces Article I's structural command that Congress make the most consequential regulatory and public policy choices.[26] Whether a broad and diverse sphere of private conduct will be subjected to federal regulation at all; what conduct will be regulated; by what instruments; and when that authority will be triggered are all legislative policy choices the Constitution assigns and reserves to Congress.

The distinction dates to the Republic's infancy: agencies may "fill up the details" of a regulatory program that Congress has designed. *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 43 (1825). Congress may not leave agencies to resolve antecedent policy questions—the "important subjects"—which "must be entirely regulated by the legislature itself." *IBID.*[27] Questions about *if* to

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[26] This structural account has academic support. *See* Chen, *supra*, at 546–49 (major questions doctrine operates as a canon of constitutional enforcement); Capozzi, *supra*, at 527–41 (doctrine enforces Article I's requirement that Congress, not the Executive, legislate on "important" subjects).

[27] *See* Chen, *supra*, at 542–44 (nondelegation's "sliding-scale" framework requires Congress to regulate "important subjects" itself while agencies

regulate, *what* to regulate, and *when* to regulate are the antecedent decisions which Article I demands that Congress decide when crafting the core elements of a major question's regulatory regime. Congress must define the policy rather than abdicate those questions to an agency.

Yet, the clarity of a congressional delegation allowing agencies to decide *which industries fall within a regulatory regime* is not the same as a clear congressional policy decision *that a particular industry falls within that regime*. The fact that Congress made a "clear statement" in TCA § 387a(b) begs the question whether Article I permitted its delegation of authority no matter how clearly articulated.

That distinction was not satisfied by Congress articulating a candid grant of boundless legislative power to an agency. If it were, Congress could always evade Article I and the major questions doctrine as its gatekeeper by articulating delegations in explicit but unbounded terms. The doctrine, instead, enforces Article I's command to Congress that it must *resolve* the subject matters of major questions, not defer legislative authority to an agency to do so.[28]

"fill up the details"); *see also* Capozzi, *supra*, at 537–38 (doctrine ensures that reaching an important subject is a choice Congress itself has made).

[28] The constitutional design presupposes that the legislative function will be exercised by the branch "in which the legislative authority necessarily predominates," not surrendered to another. *The*

1. APPLICATION OF PETITIONERS' ARGUMENTS.

No matter how clearly worded, TCA § 387a(b)'s grant of open-ended deeming authority is a broad brush—even if wielded with a steady hand.[29] The Fifth Circuit's recent opinion in *RJRT, supra.* exemplifies how Congress regulated a core part of a major question (cigarette warning labels) with a fine legislative brush.[30] *RJRT* spoke in brush-stroke terms—presciently observing that "constitutional trouble sometimes follows" when Congress legislates in broad strokes." *RJRT*, at *slip op.* at 2. This case presents that trouble.

RJRT addressed the fine brush Congress used to regulate cigarette warning labels—a core TCA purpose.[31] Congress provided the specific number

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Federalist No. 51, at 322 (James Madison) (C. Rossiter ed., 1961).

[29] Should the Court reach the merits, the Petitioners will address the many circumstances in which FDA did not wield the regulatory brush with a steady hand. *See Helix Innovations*, *supra.* which explains FDA's many regulatory challenges.

[30] A fine brush was warranted when Congress regulated cigarette warning labels. Better consumer disclosure and "appropriate regulatory controls" were core TCA purposes. *See* TCA § 387 notes 6, 8. If Congress knew how to paint with a fine brush when constructing cigarette label requirements—down to specifying their number and precise text—it certainly knew how to use the same fine brush when identifying the specific products to be regulated.

[31] TCA § 387 note 6.

and precise text of nine rotating warning labels. *RJRT* noted that "Congress legislated with precision" while leaving FDA only "limited, conditional authority" to adjust. *ID.* at *slip op.* 2.

Congress constructed the TCA against *Brown & Williamson's* Article I boundary. Congress addressed its core concerns over cigarette labels with the type of precision Article I demands. *Wayman, supra.* distinguishes the "important subjects, which must be entirely regulated by the legislature itself," from the lesser matters on which "a general provision may be made, and power given to those who are to act under such general provisions to fill up the details." 23 U.S. at 43. The dichotomy between Congress's specific legislation of a core TCA element while limiting FDA's authority satisfies *Wayman*

If Congress knew to construct the regulation of cigarette warning labels with a fine brush. Article I certainly commanded that it use that same fine brush to identify the specific products to be regulated. Deciding core "*if*, *what* and *when*" to regulate important legislative policy questions is not "fill[ing] up the details" for Article I purposes. *Wayman, supra.* at 43.

2. THE TCA'S DEEMING CLAUSE EVIDENCES THE FINE/BROAD BRUSH DICHOTOMY.

The TCA's own architecture confirms the fine/broad brush analogy. Congress legislated both precisely (fine brush) and broadly (broad brush) in the TCA's vesting provision. Congress painted with a fine brush when both defining the operative "tobacco product" term, TCA § 321(rr), and

identifying the four enumerated product subsets immediately assigned to FDA, *id*. at § 387a(b). There is no interpretive gap and no major question left open as to those product subsets. Congress made the momentous legislative policy choices—"*if*, *what* and *when* to regulate." That is the very specimen of what Article I commands and the major questions doctrine enforces when Congress confronts a matter of great consequence.

The TCA's deeming clause, however, is the antithesis of that model. The universe of "any other tobacco products" is a diverse product mosaic lying at differing positions on the FDA-recognized "continuum of harm."[32] TCA's deeming clause allowed FDA to subject those diverse products to a one-size-fits-all regulatory paradigm which fails to prioritize products or tailor their regulation to the risks they pose.[33] The regulatory regime at issue here is a fruit of that one-size-fits-all regulation of a major question.

The as-applied result of Congress's deeming authority allowed FDA to fix its own jurisdictional boundaries. That is inconsistent with Article I on its face. FDA used that authority to ignore the plain language of a core TCA purpose to "provid[e] new and flexible enforcement authority to ensure

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[32] David Spross, *FDA's CTP Acting Director Recognizes Continuum of Risk Among Tobacco Products*, CSP Daily News (Nov. 6, 2025), reporting on CTP Director Bret Koplow's October 2025 keynote presentation at FDLI Tobacco & Nicotine Products Conference.

[33] 81 FED. REG. 28,974 (May 10, 2016).

the effective oversight of efforts to develop, introduce, and promote less harmful tobacco products."[34] FDA's one-size-fits-all regulatory paradigm included harm reduction products that either did not exist, were nascent, or were not reasonably anticipated when Congress enacted the TCA.

FDA immediately subjected thousands of products to its "onerous"[35] PMTA requirement. The Framers, however, reserved that decision to Congress. Subjecting the diverse mosaic of "other tobacco products" to a comprehensive one-size-fits-all regulatory regime—and on what terms—is a major question in every sense the doctrine recognizes. This Court has marked the elements of such question—its political significance, its effect on a significant portion of the American economy, and its intrusion into areas of traditional state concern—as exhibited by FDA's singular deeming of "other tobacco products." *See West Virginia*, 597 U.S. at 743–45 (Gorsuch, J., concurring).

3. CONGRESS DID NOT DECIDE THE MAJOR QUESTION.

Whether to regulate "other tobacco products," which specific products to regulate and when to do so were core Article I elements—each enforced through *Brown & Williamson*. Article I required that Congress decide these questions. Federal regulatory regimes reaching new categories of

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[34] PUB. L. NO. 111-31, § 3(4), 123 STAT. 1776, 1782 (2009) (codified at 21 U.S.C. § 387 note 4).

[35] *Big Time Vapes*, 963 F.3d at 439.

products or conduct is itself the paradigmatic example of a major question policy decision reserved to Congress, not annexed by an agency through general language. *See Brown & Williamson*, 529 U.S. at 159–61 (whether FDA could bring tobacco within its jurisdiction); *Gonzales v. Oregon*, 546 U.S. 243, 267 (2006) (whether federal drug enforcement reached the regulation of medical practice).

Congress failed its Article I obligation when vesting FDA with the "*if* to regulate", "*what* to regulate" and "*when* to regulate" decisions as to regulating the diverse mosaic of products encompassing the TCA's open-ended deeming clause.[36] Congress painted with a fine brush when specifically identifying and prioritizing the regulation of four specific cigarette product subsets. TCA § 387a(b). That same fine brush crafted the prioritized cigarette warning labels. Article I required that Congress paint with the same fine brush to determine the "*if*, *what*, and *when*" decisions as to "other tobacco products." Review is warranted to address this question.

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[36] The Framers intended that choices of this magnitude rest with a legislature answerable to the people, so that the law and accountability for it remain joined. *See The Federalist No. 62*, at 378–80 (James Madison) (C. Rossiter ed., 1961); *The Federalist No. 63*, at 382–83 (James Madison) (C. Rossiter ed., 1961).

C. THE PANEL ERRONEOUSLY REFRAMED VDX'S MAJOR QUESTIONS DOCTRINE CHALLENGE.

The panel below recast Petitioners' major questions challenge as a nondelegation claim "foreclosed" by existing circuit precedent. App. 10a. That places an entire category of consequential *ultra vires* delegations beyond the reach of judicial review.

In addressing Petitioners' major questions challenge, the panel below noted the two respective doctrines are "closely related but distinct." App. 9a (quoting *NFIB*, 595 U.S. at 124 (Gorsuch, J., concurring)). Petitioners tracked a major questions framework by analyzing the core of an "[e]xtraordinary grant[] of regulatory authority," *West Virginia*, 597 U.S. at 724, against *Brown & Williamson* in challenging the TCA's deeming clause.

Petitioners also expressly distinguished the conflicting circuit precedent, *Big Time Vapes*,w as a case which challenged FDA's sub-delegation of deeming authority to an inferior officer. The panel acknowledged the Petitioners' statement about presenting a different constitutional question but applied a nondelegation analysis. App. 9a-10a.

The panel did not engage the Petitioners' doctrinal framing, Instead, it seized on a single sentence in their opening brief—the word "delegated"—to treat the claim as foreclosed. App. 10a. The word "delegated" does not convert a major-questions challenge into a nondelegation one. This Court's doctrinal cases all speak in "delegation" terms when asking whether Congress

"meant to confer such authority." *See e.g., West Virginia*, 597 U.S. at 723. Petitioners' arguments track that a major questions inquiry.

The stakes here transcend this case and guidance is needed on the issues presented.[37] *Brown & Williamson* requires that regulating tobacco must consider its economic, historic and political significance. 529 U.S. at 159–60. The TCA appears to be the only new regulatory regime wholly constructed in response to this Court finding its subject matter was a major question. TCA § 387a(b)'s deeming clause hands FDA open-ended authority to decide among a broad mosaic of products which ones will fall within a one-size-fits-all regime. The panel never addressed the Petitioners' core question: whether Article I required Congress, not FDA, to make that scope-defining decision. That question was beyond the scope of *Big Time Vapes*.

If challenges of this kind can be dismissed as a nondelegation claim, litigants can never test a statute's compliance with Article I in the context of major questions principles. They can never challenge statutes vesting agencies with authority to define the boundaries of their jurisdiction over

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[37] On September 28, 2026, FDA publicly announced its intention to reform its PMTA process after "carefully reviewing" its experience implementing the 2021 PMTA) rule and "recent judicial developments" including the aforementioned *Helix Innovations* suit.
https://www.fda.gov/news-events/press-announcements/fda-intends-evaluate-changes-pmta-regulatory-framework

matters of vast significance. That would leave the doctrine toothless precisely where it should bite hardest. That point makes the case prime for review. This Court's guidance is needed to confirm that the major questions doctrine enforces Article I and reaches delegations of core legislative policy elements of regulatory regimes, including scope-defining delegations.

III. THIS CASE IS AN IDEAL VEHICLE TO ADDRESS BOTH QUESTIONS PRESENTED HERE.

Petitioners have presented the Court two distinct, but intertwined questions. The first—whether FDA's comparative efficacy standard is a product standard for which the TCA required notice-and-comment rulemaking—is one the Petitioners have cleanly presented. Petitioners raised the question below; the panel squarely decided it as outcome-determinative: FDA premised its marketing denial order on VDX's failure to satisfy the comparative standard. If that FDA requirement is a product standard which the agency adopted without the rulemaking § 387g(c) demands, the denial cannot stand.

The second question is novel and tests Congress's authority to vest FDA with core structural legislative policy power over questions of great national importance. The congressional precision Article I requires when defining the TCA's "*if*, *what* and *when*" to regulate decisions is something this Court has not determined in the major questions context. The situation the Petitioners present is unique: Congress's first statutory regime constructed in response to a prior

major question finding. FDA's serial procedural missteps in implementing that regime illustrate the hazards of Congress abdicating core Article I decisions. *See* n. 3, *supra*.

The Petitioners present two exceptionally important questions of a recurring nature. This case is the appropriate vehicle for this Court to resolve those questions. Certiorari should be granted.

IV. ALTERNATIVELY, THE COURT SHOULD CONSIDER THIS PETITION IN CONJUNCTION WITH ANY PETITION IN *NICQUID*.

If the Court does not grant plenary review now, it should hold this petition pending its disposition of any petition for a writ of certiorari in *NicQuid*. Both cases concern the same FDA requirement, applied through the same informal PMTA adjudications, to the same class of non-tobacco-flavored vaping products. *NicQuid* held that the requirement is a substantive rule invalid under the APA for want of notice and comment. *NicQuid*, *slip op*. at 20–26. The panel below held that the same requirement is not a tobacco product standard subject to the TCA's rulemaking command. App. 18a, 27a. Both decisions turn on whether FDA may impose a uniform, flavor-triggered condition on market access without rulemaking—the question this Court reserved in *Wages*. 604 U.S. at 549.

Should the Court grant review in *NicQuid*, it could grant this petition as well and decide the APA and TCA questions together, with the complete statutory framework governing the

comparative-efficacy requirement before it. At a minimum, holding this petition would allow the Court to dispose of it in light of *NicQuid*, including by granting, vacating, and remanding for further consideration, rather than leaving Petitioners bound by a judgment whose reasoning may not survive the Court's resolution of the reserved question.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted. Alternatively, the Court should hold this petition pending its disposition of any petition for a writ of certiorari in *NicQuid, L.L.C. v. FDA*, No. 24-60272, and then dispose of it as appropriate.

November 17, 2026

Respectfully submitted,

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APPENDIX

APPENDIX A
OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Filed June 24, 2026
Lyle Cayce, Clerk

No. 24-60537

VDX DISTRO, INCORPORATED; VAPETASTIC, L.L.C.,

Petitioners,

versus

UNITED STATES FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES*,

Respondents.

On Petition for Review
of an Order of the Food & Drug Administration
Agency No. PM0002351

Before Elrod, *Chief Judge*, Smith, and Wilson, *Circuit Judges*.

Cory T. Wilson, *Circuit Judge*:

Use of e-cigarettes has been on the rise in recent years, especially among young people. This case is one of numerous disputes between the United States Food & Drug Administration (FDA) and e-cigarette companies contesting the agency's efforts to balance between discouraging youth adoption of e-cigarettes and encouraging adult cigarette smokers to switch to relatively less harmful e-cigarettes—all in view of the public health policy preferences enacted by Congress in the Family Smoking Prevention and Tobacco Control Act (TCA). Petitioner VDX Distro, Inc. (VDX) is one such company. It manufactures e-cigarette products and sells them to retailers including Vapetastic, LLC, also a petitioner here.

Under the TCA, e-cigarette manufacturers cannot market their products without FDA approval. So VDX applied to FDA to obtain marketing authorization for VDX's menthol-flavored e-cigarette products.

In FDA's view, non-tobacco-flavored e-cigarettes are especially dangerous for minors because those e-cigarettes are more enticing than tobacco-flavored ones. So under the agency's "comparative-efficacy standard," marketing applicants for non-tobacco-flavored e-cigarettes must show an advantage over tobacco-flavored e-cigarettes in encouraging adult cigarette smokers to "go digital"—*i.e.*, to switch to e-cigarettes—or to quit altogether. FDA denied VDX's application after determining that the benefits of VDX's menthol-flavored e-cigarette products to adult smokers did not outweigh the countervailing risks to youths. VDX and Vapetastic petition our court for review of that decision. We deny the petition.

I.

A.

Through the TCA, Congress gave FDA "the power to regulate the manufacturing, marketing, sale, and distribution of tobacco products." *FDA v. Wages & White Lion Invs., LLC*, 604 U.S. 542, 551 (2024). The TCA granted FDA authority over "cigarettes, cigarette tobacco, roll-your- own tobacco, and smokeless tobacco," as well as any other product that FDA "by regulation deems" to be a tobacco product. *Id.* (citing 21 U.S.C. § 387a(b)). In 2016, FDA issued a rule deeming e-cigarettes to be tobacco products. *Id.* at 555; 81 Fed. Reg. 29028 (May 10, 2016.

The TCA prohibits manufacturers from marketing tobacco products without FDA authorization. 21 U.S.C. § 387j(a)(2)(A). A manufacturer can obtain authorization by submitting a premarket tobacco product application. *Id.* § 387j(c)(1)(A)(i).[1] The application process is "onerous, requiring manufacturers to gather significant amounts of information." *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 439 (5th Cir. 2020). There are a few ways that FDA can deny a premarket application, but only two are relevant here.

First, FDA can deny applications via the TCA's rulemaking provision. The TCA empowers FDA to promulgate "tobacco product standards." 21 U.S.C.

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[1] The TCA "establishes a handful of other authorization pathways for new tobacco products," but those alternatives are irrelevant here. *Wages*, 604 U.S. at 551 n.1.

§ 387g(a)(3). And FDA "shall deny" a premarket application if the proposed product does not conform to any "tobacco product standard in effect under section 387g." 21 U.S.C. § 387j(c)(2)(D). The TCA itself contains two tobacco product standards: The statute bans cigarettes that contain "artificial or natural flavor[s] (other than tobacco or menthol)," and it prohibits manufacturers from using tobacco that "contains a chemical pesticide residue level greater than is specified by any tolerance applicable under Federal law." 21 U.S.C. § 387g(a)(1). Before adopting any other tobacco product standards, FDA must publish a notice of proposed rulemaking and invite comments. *Id.* § 387g(c).

The second mode is through the TCA's adjudicatory framework. FDA "shall deny" a premarket application that does not indicate that marketing the tobacco product would be "appropriate for the protection of the public health" (APPH). 21 U.S.C. § 387j(c)(2)(A). To determine whether a product is APPH, the TCA requires FDA to consider "the risks and benefits of the population as a whole, including users and nonusers of the tobacco product." *Id.* § 387j(c)(4). The TCA further clarifies that FDA must consider "the increased or decreased likelihood that existing users of tobacco products will stop using such products and . . . [that] those who do not use tobacco products will start using such products." *Id.* In plain English, the TCA aims to maximize the chances that smokers will quit and minimize the risk that non-smokers will start.

B.

In 2017, FDA noted an "alarming increase" in the use of e-cigarettes by "middle and high school students." FDA responded by investigating reports of e-cigarette sales to minors. FDA also issued warning letters to various manufacturers, distributors, and retailers that sold e-cigarette products with "advertising that resemble[d] kid-friendly food products, such as juice boxes, candy, or cookies." However, in 2018, "FDA continued to receive information underscoring the problem of youth use of [e- cigarettes]." By 2019, "two of the largest surveys of tobacco use among youth found that e-cigarette use ha[d] hit the highest levels ever recorded."

In April 2020, FDA published a guidance document laying out the agency's enforcement priorities for e-cigarettes (the 2020 Guidance). The 2020 Guidance stated that FDA would "exercise its enforcement authorities with respect to particular products . . . on a case-by-case basis, informed by the enforcement priorities described in this Final Guidance." FDA was especially concerned with the popularity of flavored e-cigarette products with youth because "[r]esearch has long shown that flavors increase youth appeal of tobacco products, including [e-cigarettes]." The 2020 Guidance noted that youth use of menthol-flavored e-cigarettes was not as high as youth use of other flavored e-cigarettes (such as mint- and fruit-flavored), and that young people preferred cartridge-based e-cigarettes as opposed to other types. Therefore, the 2020 Guidance stated that FDA would prioritize enforcement against "[a]ny flavored, cartridge-based [e-cigarette] product (other than a tobacco-

or menthol-flavored product)." In particular, FDA would prioritize e-cigarettes that were "targeted to minors or whose marketing is likely to promote use of [e-cigarettes] by minors."

By October 2022, internal memoranda indicate that FDA's approach to menthol-flavored e-cigarettes had shifted. The agency had hoped that menthol-flavored e-cigarettes would have less appeal to youth than other flavored e-cigarettes and would provide a suitable substitute for adults who smoke menthol-flavored combustible cigarettes. But after further study, FDA noted a "lack of robust evidence of the actual differential use of menthol-flavored [e-cigarettes]" in reducing cigarette use per day. For menthol cigarette smokers who sought to quit or switch to e-cigarettes, the "nationally representative data" had not shown that they preferred menthol-flavored e-cigarettes to tobacco-flavored ones. Therefore, FDA stated that its approach to menthol-flavored e-cigarettes should be the same as with other non-tobacco-flavored e-cigarettes "with respect to the evidence of adult benefit."[2]

C.

VDX Distro, Inc. manufactures e-cigarette products—specifically, nicotine-infused liquids that go inside of e-cigarettes— and sells them to e-cigarette retailers including Vapetastic, LLC. VDX submitted a premarket application to FDA

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[2] According to FDA, the approach reflected in the internal memoranda was "formulated in the course of FDA's evaluation of the Logic menthol applications." *See Logic Tech. Dev. LLC v. FDA*, 8 F.4th 837 (3d Cir. 2023).

requesting marketing authorization for its "Four Seasons" e-cigarette products, many of which were menthol-flavored. FDA denied VDX's application as to the menthol-flavored e-cigarette products.[3]

FDA's written explanation for the denial is lengthy and technical, but the bottom line turns on FDA's application of a balancing test. While the evidence showed that non-tobacco-flavored e-cigarettes—including menthol—have a "known and substantial risk of youth initiation and use," *tobacco*-flavored e-cigarettes "have not been shown to present the same risks to youth." Therefore, FDA determined that the marketing of non-tobacco- flavored e-cigarettes is "APPH only if the evidence shows a benefit to adults who smoke as compared to tobacco-flavored [e-cigarettes]." In other words, to be APPH, a non-tobacco-flavored e-cigarette must have an advantage over tobacco-flavored ones when it comes to getting adult cigarette smokers to quit altogether or "go digital." Only then would a non-tobacco-flavored e-cigarette's benefit to adults outweigh its risk to minors. The parties call this the "comparative-efficacy standard."

Applying the comparative-efficacy standard, FDA determined that VDX's premarket application "lack[ed] sufficient evidence" to demonstrate that its menthol-flavored e-cigarette products will "provide a benefit to adult users that

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[3] FDA also denied VDX's premarket application as to the flavored e-cigarette products that were neither tobacco- nor menthol-flavored, but the petition before us concerns only FDA's denial as to the menthol-flavored e-cigarette products.

would be adequate to outweigh the risks to youth." On that basis, FDA concluded that allowing VDX to market its menthol-flavored e-cigarette products would not be APPH and therefore denied VDX's premarket application.

II.

VDX and Vapetastic assert four challenges in their petition for review[4]. First, they argue that the major questions doctrine prohibits FDA's assertion of regulatory authority over e-cigarettes. Second, Petitioners contend that the TCA's APPH standard is unconstitutionally vague. Third, Petitioners maintain that FDA's comparative-efficacy standard is actually a tobacco product standard that FDA adopted in violation of the TCA's notice-and-comment rulemaking requirements. Finally, Petitioners insist that FDA arbitrarily and capriciously applied the APPH standard when adjudicating VDX's premarket application. We address each claim in turn.

A.

Petitioners' first claim ostensibly anchors itself to the major questions doctrine. They assert that "Congress's delegation of deeming authority violated the major questions doctrine" because the TCA allows FDA broad discretion to "deem" products to be "tobacco products," thus subjecting

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[4] Venue is proper in our court because Vapetastic is a Texas LLC. *See Shenzhen IVPS Tech. Co., Ltd. v. FDA*, 148 F.4th 306, 312 (5th Cir. 2025) ("[If] one of the Petitioners has its principal place of business within the Fifth Circuit, venue is proper under Section 387*l*(a)(1)(B).").

those products to the TCA's requirements. *See* 21 U.S.C. § 387a(b). Despite Petitioners' characterization, their argument in substance invokes not the major questions doctrine but the nondelegation doctrine. But the two doctrines are not interchangeable, and Petitioners' nondelegation challenge is squarely foreclosed.

The major questions and nondelegation doctrines are "closely related" but distinct. *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab.*, 595 U.S. 109, 124 (2025) (Gorsuch, J., concurring). While the major questions doctrine "guard[s] against unintentional, oblique, or otherwise unlikely delegations of legislative power," the nondelegation doctrine "ensures democratic accountability by preventing Congress from intentionally delegating its legislative powers to unelected officials." *Id.* at 124–25. Under the major questions doctrine, an agency must point to "clear congressional authorization" rather than "a merely plausible textual basis" when it asserts "[e]xtraordinary grants of regulatory authority." *West Virginia v. EPA*, 597 U.S. 697, 723 (2022) (quotation omitted). Under the nondelegation doctrine, Congress may vest discretion in executive agencies, but it cannot give away its legislative power; courts must ask "whether Congress has set out an 'intelligible principle' to guide what it has given the agency to do." *FCC v. Consumers' Rsch.*, 606 U.S. 656, 672 (2025) (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)).

Though Petitioners repeatedly reference the major questions doctrine, they do not really make a major questions argument. They assert that

"Congress impermissibly delegated legislative authority to FDA to determine which products it would regulate." That is a textbook nondelegation argument, and our court has already rejected it. In *Big Time Vapes, Inc. v. FDA*, an e-cigarette manufacturer "sued the FDA, contending that the TCA unconstitutionally delegated to [FDA] the power to deem tobacco products subject to the Act's mandates." 963 F.3d at 440. This court disagreed, holding instead that "Congress plainly limited the authority that it delegated." *Id.* at 445. Petitioners' argument is on all fours with *Big Time Vapes*, so it is foreclosed, in whatever wrapping it is packaged.

B.

As explained earlier, the TCA requires FDA to deny premarket applications unless "permitting such tobacco product to be marketed would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). Petitioners contend that this standard is unconstitutionally vague. But a statute is open to a vagueness challenge only when it is arguably unclear as to what conduct it prohibits. The APPH standard does not run afoul of this guardrail.

"Vague statutes violate due process, because laws must 'give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly.'" *Ford Motor Co. v. Tex. Dep't of Transp.*, 264 F.3d 493, 509 (5th Cir. 2001) (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)). But "[b]efore a penalty, whatever its nature, creates urgent need for notice, that penalty must attach to conduct." *Jones v. City of Lubbock*, 727 F.2d 364,

373 (5th Cir. 1984). If a law "imposes neither regulation of nor sanction for conduct," then "no necessity exists for guidance so that one may avoid the applicability of the law." *Boutilier v. INS*, 387 U.S. 118, 123 (1967). In short, "[a]bsent an effect on conduct, a statute's standard is not susceptible to attack as vague." *Jones*, 727 F.2d at 373.

The TCA's APPH standard does not, by itself, prohibit anything. It is instead an adjudicatory standard by which FDA must assess applications for marketing authorization. If FDA determines that marketing a proposed tobacco product would not be APPH, that determination does not mean that the product manufacturer has violated any laws; nor does it subject the manufacturer to any penalties. Rather, it is the TCA's prohibition of unauthorized marketing—not the APPH standard—that constrains a manufacturer's actions. And it is perfectly clear what a manufacturer must do to avoid violating the TCA: Do not market e-cigarettes without FDA preapproval. Because the APPH standard prohibits no conduct, it cannot be challenged as unconstitutionally vague.

C.

Under FDA's comparative-efficacy standard, the marketing of a non- tobacco-flavored e-cigarette will not be considered APPH unless the "evidence shows a benefit to adults who smoke as compared to tobacco- flavored [e-cigarettes]" because tobacco-flavored e-cigarettes do not pose the same risks to youths as non-tobacco-flavored ones. Petitioners assert that this is "a disguised tobacco product standard adopted contrary to the

TCA" because FDA circumvented the TCA's notice-and-comment requirements for rulemaking. Petitioners are incorrect. The comparative-efficacy standard is not a "tobacco product standard" as the TCA delineates them; it is instead a methodology developed by FDA to apply the TCA's APPH standard.

As discussed, the TCA allows FDA to promulgate "tobacco product standards." 21 U.S.C. § 387g(a)(3). Before doing so, FDA must publish a notice of proposed rulemaking and invite public comment. *Id.* § 387g(c). FDA "shall deny" premarket applications for tobacco products that do not conform to any "tobacco product standard in effect under section 387g." *Id.* § 387j(c)(2)(D). The TCA does not define "tobacco product standard," but the rest of the statute provides illuminating context.

In 21 U.S.C. § 387g(a)(4), the TCA outlines the "[c]ontent of tobacco product standards," listing several "provisions" that a tobacco product standard might encompass. These provisions include various aspects of tobacco products, such as "nicotine yields"; "reduction or elimination of other constituents, including smoke constituents"; "testing," "measurement," and "sale and distribution"; and "the form and content of labeling for the proper use" of tobacco products. *Id.* The TCA further specifies that parties may submit specific evidence to FDA to contest a "determination, set forth in a proposed tobacco product standard in a proposed rule," that it would be APPH to "require the reduction or elimination of an additive, constituent, or other component of a tobacco product." *Id.* § 387g(a)(3)(B)(iii). A

consistent theme of these clauses is that tobacco product standards would draw hard-and-fast lines as to certain attributes of tobacco products, including their flavoring.

That reading gains support from the two tobacco product standards actually enumerated in the TCA.[5] The first is a "[s]pecial rule for cigarettes": They "shall not contain . . . an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, [&c.]." *Id.* § 387g(a)(1)(A). The second is an "[a]dditional special rule" providing that tobacco product manufacturers "shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco." *Id.* § 387g(a)(1)(B). In short, the TCA's two tobacco product standards (1) prohibit cigarettes from having any flavors except tobacco or menthol, and (2) set an upper limit on how much pesticide residue is allowed in tobacco products.

The Federal Register contains four proposed tobacco product standards propounded by FDA, all akin to the two Congress enacted in § 387g(a)(1). Each purports to derive its implementing

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[5] Under the TCA, the Secretary of the Department of Health and Human Services (or FDA, as the Secretary's designee) "may adopt tobacco product standards *in addition to those in paragraph (1)* if the Secretary finds that a tobacco product standard is [APPH]." 21 U.S.C. § 387g(a)(3)(A) (emphasis added).

authority from § 387g, and each bolsters our reading of what qualifies as a tobacco product standard under the statute. The first is a "tobacco product standard that would establish a limit of N-nitrosonornicotine (NNN) in finished smokeless tobacco products." 82 Fed. Reg. 8004-1 (Jan. 23, 2017). The second "would prohibit characterizing flavors (other than tobacco) in all cigars and their components and parts." 87 Fed. Reg. 26396-01 (May 4, 2022). The third is a "tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes." 87 Fed. Reg. 26454-01 (May 4, 2022). And the fourth "would regulate nicotine yield by establishing a maximum nicotine level in cigarettes and certain other combusted tobacco products." 90 Fed. Reg. 5032-01 (Jan. 16, 2025).[6] As with the standards denoted in

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[6] None of these four proposed rules has been finalized; the federal government's regulatory website indicates that all four remain open. *See* Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products (https://www.regulations.gov/docket/FDA-2016-N-2527) [https://perma.cc/26LS- GRZB]; Tobacco Product Standard for Characterizing Flavors in Cigars (https://www.regulations.gov/docket/FDA-2021-N-1309) [https://perma.cc/6JGW- EMCG]; Tobacco Product Standard for Menthol in Cigarettes (https://www.regulations.gov/docket/FDA-2021-N-1349) [https://perma.cc/752K- ZCKW]; Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products (https://www.regulations.gov/docket/FDA-2024-N-5471) [https://perma.cc/S6FP-3USW]; *but see* 90 Fed. Reg. 45515-01 (Sept. 22, 2025) (indicating that the latter two proposed rules have been withdrawn).

the TCA itself, these four standards proposed by FDA all set objective, categorical limits on the tobacco products targeted by them (*e.g.*, smokeless tobacco, cigars, cigarettes). This means that, for instance, even if a manufacturer were to provide overwhelming evidence that marketing a strawberry-flavored cigarette would be APPH, the question is a non-starter; § 387g(a)(1)(A)'s tobacco product standard forecloses any question of FDA's approval.

FDA's comparative-efficacy standard is qualitatively different. It channels the flexible adjudicatory discretion that a tobacco product standard would usurp. With the comparative-efficacy standard, manufacturers can obtain marketing approval; as always, they need only show that marketing their product would be APPH. The difference is that for *non-tobacco*-flavored e-cigarettes, FDA has decided to construe the APPH standard's pliable threshold more narrowly than for tobacco-flavored ones. In other words, the comparative-efficacy standard is simply a more exacting interpretation of the TCA's APPH standard as it pertains to non-tobacco- flavored e-cigarettes. True enough, FDA employs that interpretation across-the-board in its evaluation of applications for non-tobacco-flavored e-cigarette products. That uniformity may be tantamount to FDA's application of a rule—a question we do not address in today's case—but it does not render the comparative-efficacy standard a "tobacco product standard" within the meaning of the TCA. The comparative-efficacy standard is a balancing test,

not a ban.[7]

Interpreting the TCA as allowing flavor-based comparisons is consistent with the Supreme Court's emphasis on the APPH standard's "inherently comparative judgment," one that "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. The TCA charges FDA with making those comparisons, and we see no reason why the APPH's comparative exercise cannot focus on flavor— especially given FDA's empirical findings about the different levels of risk posed by different flavors. As many of our sister circuits have concluded, FDA's choice to "compare[ ] the claimed cessation benefits of flavored and non-flavored products . . . is precisely the type of analysis the statute calls for." *Prohibition Juice Co. v. FDA*, 45

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[7] Indeed, a few e-cigarette manufacturers *have* gotten marketing approval for menthol-flavored e-cigarettes even with the comparative-efficacy standard in play. This outcome, even if vanishingly rare, would not be possible at all under a tobacco product standard. *See* Food & Drug Administration, *FDA News Release: FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific Review* (June 21, 2024), https://www.FDA.gov/news-events/press-announcements/FDA-authorizes-marketing-four-menthol-flavored-e-cigarette-products-after-extensive-scientific [https://perma.cc/SY4U-PTH2].

F.4th 8, 19 (D.C. Cir. 2022).[8] Accordingly, we reject Petitioners' suggestion that *any* flavored-based distinctions are tantamount to tobacco product standards. On the contrary, FDA's flavored-based comparative assessment flows from the TCA itself.

Our conclusion is further bolstered by the Supreme Court's recent reiteration that "agencies may generally develop regulatory standards through either adjudication or rulemaking." *Wages*, 604 U.S. at 582 (citing *SEC v. Chenery Corp.*, 332 U.S. 194, 202–03 (1947)). While FDA could have opted for rulemaking, "FDA had discretion to work out the meaning of the TCA's comparative standard when evaluating premarket tobacco product applications." *Id.* That is what FDA did with its comparative-efficacy standard; the agency chose adjudication as its preferred route for comparatively evaluating the distinctive dangers of non-tobacco-flavored e- cigarettes. And while FDA uniformly applies the standard across adjudications, nothing in the TCA prevents FDA from doing so. Because the comparative-efficacy standard is not a tobacco product standard, FDA's utilization of the comparative-efficacy standard did not violate the TCA's notice-and-comment

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[8] *See also Magellan Tech., Inc. v. FDA*, 70 F.4th 622, 631 (2d Cir. 2023); *Liquid Labs LLC v. FDA*, 52 F.4th 533, 542 (3d Cir. 2022); *Avail Vapor, LLC v. FDA*, 55 F.4th 409, 427–28 (4th Cir. 2022); *Gripum, LLC v. FDA*, 47 F.4th 553, 559 (7th Cir. 2022); *Lotus Vaping Techs., LLC v. FDA*, 73 F.4th 657, 661 (9th Cir. 2023).

requirements.[9]

D.

Turning to FDA's adjudication of VDX's premarket application, the TCA directs that we review FDA's denial of an application in accordance with § 706 of the Administrative Procedure Act (APA). 21 U.S.C. § 387*l*(b). The APA requires the court to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "The APA's arbitrary-and- capricious standard requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). An agency must "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *BNSF Ry. Co. v. Fed. R.R. Admin.*, 62 F.4th 905, 910 (5th Cir. 2023) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

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[9] Petitioners' TCA notice-and-comment attack on the comparative-efficacy standard is distinct from a claim based on the APA's notice-and-comment provisions. Amici curiae in support of Petitioners lodge both arguments, but Petitioners make only the former. We therefore leave for another day the merits of an APA notice-and-comment argument. *But see RJ. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 192–94 (5th Cir. 2022). As explained *supra*, the TCA's particular statutory framework and context drive our analysis of the TCA notice-and-comment issue before us.

Petitioners contend that FDA arbitrarily applied the APPH standard to VDX's premarket application by: (1) basing its analysis on outdated data; (2) failing to adhere to the TCA's "population as a whole" requirement; and (3) arbitrarily applying the APPH standard to VDX's marketing plan. We consider each contention in turn.

1.

Petitioners first argue that FDA improperly relied on "stale youth use data" in denying VDX's application. True enough, more recent data show significant reductions in youth e-cigarette use. Yet, according to Petitioners, FDA nevertheless "continued to regulate as if it [was] still 2019 and the reductions in youth use never occurred." In short, Petitioners contend that FDA acted arbitrarily because it had no good reason to stay the course as the data changed.

Not so. The record shows that FDA was well aware that youth e- cigarette use had been declining since 2019; indeed, the agency affirmatively took credit for it. In FDA's view, its choice to prioritize non-tobacco- flavored e-cigarettes "contributed to the decline in youth use." Even then, FDA says, the problem persisted: Youth use of e-cigarettes remained at worryingly high levels. And of the youths who reported using e-cigarettes in 2022, about 27% used menthol-flavored ones. FDA therefore decided to stay the regulatory course.

"Black-letter administrative law instructs that when an agency makes. . . scientific judgments, . . . a reviewing court must be at its 'most deferential.'" *Seven Cnty. Infrastructure Coal. v.*

Eagle Cnty., 605 U.S. 168, 182 (2025) (quoting *Baltimore Gas & Elec. Co v. Nat'l Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983)). And an agency has "broad discretion" to choose among its regulatory priorities. *See Massachusetts v. EPA*, 549 U.S. 497, 527 (2007). We therefore decline Petitioners' invitation to second-guess FDA's continued prioritization of enforcement against non-tobacco-flavored e- cigarettes—though coincident with a decline in youth e-cigarette use—as the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action." *BNSF Ry. Co.*, 62 F.4th at 910.

2.

Petitioners also argue that FDA ignored the TCA's requirement that FDA must make its APPH determination based on "the risks and benefits to the population as a whole." 21 U.S.C. § 387j(c)(4). In Petitioners' telling, FDA improperly "focus[ed] wholly on two subpopulations and subfactors: the proven benefit in transitioning adult smokers versus the risks of youth access."

But Petitioners' position runs contrary to the TCA, which allows FDA to focus on particular subpopulations. The TCA requires FDA to assess "the risks and benefits to the population as a whole, *including users and nonusers of the tobacco product*." *Id.* (emphasis added). Further, the TCA commands FDA specifically to consider "the increased or decreased likelihood" that "existing users of tobacco products will stop using such products" and that "those who do not use tobacco products will start using such products." *Id.* This indicates that Congress wanted to ensure that

FDA considers both sides of the user/non-user equation when estimating a tobacco product's net impact, not that Congress wanted to block FDA from examining effects on subpopulations.

When it came to assessing the benefits and risks of flavored e- cigarettes, FDA made a reasonable decision as to which smokers are likely to stop and which non-smokers are likely to start. To gauge benefits to smokers, FDA's focus is on adults who smoke combustible cigarettes. And for risks to non-smokers, FDA focused on youth adoption as a particular concern. By focusing on these two subpopulations, FDA reasonably aimed to maximize the overall positive impact on the "population as a whole." On the record before us, that approach was not arbitrary and capricious.

3.

Petitioners last argue that FDA arbitrarily applied the APPH standard to VDX's marketing plan. Petitioners offer two reasons why, but neither is persuasive.

First, Petitioners assert that FDA "refused to review VPX's [*sic*] marketing plan for the sake of efficiency." Granted, FDA previously took this tack. In the agency's 2021 denial of VDX's earlier application for non- tobacco, non-menthol-flavored e-cigarette products, FDA stated that "for the sake of efficiency, the evaluation of the marketing plans in applications will not occur at this stage of review" because FDA had seen no "access restrictions that, to date, have been successful in decreasing the ability of youth to obtain and use [e-cigarettes]."

But that is not what FDA did in this case. In FDA's denial of VDX's current application for menthol-flavored e-cigarette products, FDA noted that "given the concerns expressed by certain federal courts, . . . FDA is now reviewing all applicant-proposed marketing restrictions and mitigation measures." And FDA indeed reviewed VDX's marketing plan. Thus, Petitioners can challenge the substance of FDA's review of VDX's marketing plan, but they cannot challenge the fact that FDA reviewed it.

Second, Petitioners contend that FDA did not adequately explain its conclusion that VDX's marketing plan was insufficient. We disagree. FDA stated that VDX's marketing plan "did not propose any novel or materially different measures from those that FDA has previously considered and found insufficient." FDA further explained that while sales restrictions can help reduce youth access, youths obtain e-cigarettes despite sales restrictions because most youth e-cigarette users do not buy them; they often get e- cigarettes from friends or family, or steal them. Therefore, mere "sales access restrictions do not in themselves provide enough assurance of a sufficient reduction in youth use to mitigate the risk." Similarly, FDA explained that restrictions on advertising and promotion do "not directly prevent youth use," such that their utility is limited. "To date," the "only measures" that FDA has found to have provided sufficient safeguards from the risk of youth use are "device access restrictions" such as "identification by fingerprint or other biometric parameters in order to unlock and use a tobacco product." VDX's marketing plan did not include

those safeguards.

FDA's rationale was not arbitrary and capricious. FDA explained that "point-of-sale restrictions and marketing changes did not sufficiently protect youth, as youth frequently accessed [e-cigarette] products after the point of sale." *SWT Glob. Supply, Inc. v. FDA*, 139 F.4th 957, 964 (8th Cir. 2025). And FDA conveyed that "restrictions beyond the point of sale—for example, biometric use barriers—could combat the problem." *Id.* At bottom, FDA "articulate[d] a satisfactory explanation for its action." *BNSF Ry. Co.*, 62 F.4th at 910 (quotation omitted).

III.

In sum, all four of Petitioners' challenges are unsuccessful. First, Congress did not violate the nondelegation doctrine—or the major questions doctrine—by granting FDA the authority to deem products to be "tobacco products" for purposes of TCA regulations. Likewise, the TCA's APPH standard is not subject to a vagueness attack because it does not prohibit any conduct.

Nor did FDA's adoption of the comparative-efficacy standard violate the TCA's notice-and-comment rulemaking requirements. That is because the comparative-efficacy standard is not a "tobacco product standard" within the meaning of the TCA. Rather, it is a rubric for applying the APPH calculus's "inherently comparative judgment," *Wages*, 604 U.S. at 578–79, to non-tobacco-flavored e-cigarettes—a balancing test, not a ban.

Finally, FDA did not arbitrarily and capriciously apply the APPH standard to VDX's premarket application. The record indicates that FDA provided a reasoned explanation for its denial of that application.

PETITION DENIED

APPENDIX B
JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT
Filed June 24, 2026
Lyle Cayce, Clerk

No. 24-60537

VDX DISTRO, INCORPORATED; VAPETASTIC, L.L.C.,

Petitioners,

versus

UNITED STATES FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES*,

Respondents.

On Petition for Review
of an Order of the Food & Drug Administration
Agency No. PM0002351

JUDGMENT

Before Elrod, *Chief Judge*, Smith, and Wilson, *Circuit Judges*.

This cause was considered on the petition of VDX Distro, Incorporated and Vapetastic, L.L.C. for review of an order of the Food & Drug Administration and was argued by counsel.

IT IS ORDERED and ADJUDGED that the petition for review is DENIED.

IT IS FURTHER ORDERED that petitioners pay to respondents the costs on appeal to be taxed by the Clerk of this Court.

The judgment or mandate of this court shall issue 7 days after the time to file a petition for rehearing expires, or 7 days after entry of an order denying a timely petition for panel rehearing, petition for rehearing en banc, or motion for stay of mandate, whichever is later. See Fed. R. App. P. 41(b). The court may shorten or extend the time by order. See 5th Cir. R. 41 I.O.P.

SEAL

Certified as a true copy and issued as of the mandate on Aug 28, 2026

Attest: Lyle C. Cayce

Clerk, U.S. Court of Appeals, Fifth Circuit

APPENDIX C
ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT DENYING PANEL AND *EN BANC* REHEARING

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT
Filed August 21, 2026
Lyle Cayce, Clerk

No. 24-60537

VDX DISTRO, INCORPORATED; VAPETASTIC, L.L.C.,

Petitioners,

versus

UNITED STATES FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES*,

Respondents.

On Petition for Review
of an Order of the Food & Drug Administration
Agency No. PM0002351

ON PETITION FOR REHEARING AND REHEARING EN BANC

Before Elrod, *Chief Judge*, and Smith and Wilson, *Circuit Judges*. Per Curiam:

The petition for panel rehearing is DENIED. Because no member of the panel or judge in regular active service requested that the court be polled on rehearing en banc (Fed. R. App. P.40 and 5th Cir. R.40), the petition for rehearing en banc is DENIED.

APPENDIX D
Ryan Chalmé Fifth Circuit Declaration

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

VDX Distro, Inc.
-and-
Vapetastic, LLC

Petitioners

vs. No. 24-60537

U.S. Food and Drug Administration;
Robert Califf, Commissioner;
U.S. Department of Health and
Human Services;
Xavier Becerra, Secretary,

Respondents.

DECLARATION OF RYAN CHALME

I, Ryan Chalme, declare and state as follows:

1. I am the sole shareholder, officer and director of VDX Distro, Inc. (VDX Distro), a Nevada corporation, which has its principal office in Sun Valley (Los Angeles County), California.

2. I incorporated VDX on November 28, 2017 and it is the direct successor to Vapor Delux, Inc. (Vapor Delux) which I also solely owned. I incorporated Vapor Delux as a California domestic corporation in May 2013. I managed the day-to-day operations of Vapor Delux and have done so for VDX since its founding.

3. In 2013, Vapor Delux developed a line of its own branded flavored e-liquid products for use in open-system vaping products, described below including menthol flavored and menthol tobacco flavored e-liquids.

4. After Vapor Delux transitioned its operations to VDX, I rebranded the Vapor Delux products to the name "Four Seasons." Attachment 1 hereto are true and accurate digital images which depict the trade dress (branding and labeling) of the Four Seasons products which are at issue in his case. I specifically designed the trade dress of the Four Seasons products to ensure they appealed only to VDX's adult customers. The Four Seasons branding utilizes what I consider to be the cleanest trade dress in the vaping products industry and does not contain things like cartoons, bright colors, images or messages which youth might find appealing.

5. The Four Seasons e-liquid products which VDX manufactures contain a mixture of propylene glycol, vegetable glycerin, food-grade flavorings. In some instances, the e-liquid products contain freebase or salt nicotine derived from tobacco. VDX manufactures its Four Seasons menthol and tobacco nicotine line of products in two different variations: (a) 30mg/ml and 50mg/ml salt nicotine concentrations in 30 ml bottles and (b) 3mg/ml, 6mg/ml, 12mg/ml, and 18mg/ml freebase nicotine concentrations in either 30ml or 60ml bottles. VDX also offers its menthol and tobacco menthol products without nicotine in 30ml and 60ml bottles.

6. From my long-time experience in the vaping products industry, I can confirm that industry stakeholders have segregated themselves into two distinctive market segments: the "open-system" and "closed-system" segments which generally tracks the character of the product manufacturers. Open-system products, on the other hand, are generally manufactured by small, privately-owned companies, like VDX, who had no prior history in the tobacco business. Closed-system products are generally manufactured and distributed by legacy tobacco companies. Many open-system product manufacturers are former smokers, like me, who used earlier versions of vaping products to quit smoking.

7. Open-system and closed-system product are also differentiated by the products' respective retail channels (general retail channels for closed-system products and specialty retail stores for open-system products).

8. From my experience in the vaping products industry, I can also confirm the market segmentation is further differentiated by the physical characteristics of vaping products. Open-system devices are generally larger in size than closed-system devices and rely on: (1) higher-powered, rechargeable lithium batteries which are either replaceable or self-contained within the device; (2) computer circuitry which allows the independent regulation of both the device thermal and wattage parameters; and (3) interchangeable and refillable e-liquid tanks (referred to as atomizers) as key elements. These elements allow consumers significant freedom to customize their devices. On the other hand, closed-system

products have: (1) a small device size and (2) either a disposable pre-filled cartridge or pod which offer e-liquid in a limited variety of flavor choices.

9. The small device size of closed-system products, their easy of use, and ease of purchase at non- age-restricted stores led to them becoming the overwhelming choice of youths, as evidenced by the 2023 National Youth Tobacco Survey (NYTS).[1]

10. VDX's Four Seasons menthol and menthol tobacco vaping products are sold exclusively in specialty retail stores (*i.e.* vape shops) or online retail portals devoted to the sale of open-system vaping products which enforce age-identification policies. The Petitioner, Vapetastic, LLC, a Texas vaping products specialty retailer, is an example of the type of specialty stores which VDX has sold, and currently sells, its Four Seasons menthol and menthol tobacco products.

11. To my knowledge, VDX's Four Seasons menthol and menthol tobacco vaping products have never been the subject of an underage sale violation found by either a federal, state, or local regulatory authority.

12. VDX filed its pre-market tobacco product application (PMTA) on September 9, 2020 covering its Four Seasons menthol and menthol tobacco flavored vaping products.

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[1] Birdsey, J., *et al. Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023*. MMWR Morb. Mortal Wkly. Rep. 2023;72:1173–1182 at Table 3.

13. When it became clear that VDX would be required to prepare and submit a PMTA to FDA for its e-liquid products in order to keep selling them in the United States, the company embarked on extensive efforts in conjunction with Elixa Health Associates in Anaheim, California to prepare an appropriate PMTA that would provide the information FDA had indicated was necessary in its final PMTA guidance document, its PMTA rule, and its other pre-PMTA dealings with vaping industry stakeholders. VDX's PMTA took more than a month to prepare and comprised 300 megabytes of data.

14. The marketing plan which VDX filed in support of its PMTA specified that its target customer base is adult smokers 35 years of age and older, specifically focusing on male smokers ranging from 35-45 years old in higher income groups. Attachment 2 hereto is the VDX marketing plan filed in support of its PMTA.

15. VDX's marketing plan, which it understood from FDA's pre-PMTA dealings with the vape industry would sufficient, described how it avoided marketing vapor products to youths and the steps it took to ensure they do not have the ability to purchase its products. VDX's marketing plan included the representation that it distributed vaping products through marketing channels which catered to adult customers. It did so by limiting its affiliation to partners who cater to adults over 35 years of age to preserve its brand identity as an adult-oriented product.

16. To that end, VDX's marketing plan detailed how it refrained from using partners, sponsors,

influencers, bloggers, or brand ambassadors to advertise or promote its products because these are all means of promoting products to youths. Instead, VDX constrains its marketing efforts to direct email campaigns targeted at age-verified users and verified wholesale accounts. VDX also limits its promotion of vaping products to business-to-business environments like business-to-business tradeshows. Attachment 3 hereto is a true and accurate excerpt of the current marketing brochure which VDX utilizes at tradeshows and in marketing to distributors and retailers for its menthol and menthol tobacco vaping products.

17. The VDX marketing plan also addressed how it seeks to prevent youth access and use, including:

- limiting its retail sales channels to adult-only retail establishments and online retail portals with adequate online age verification software which rely upon independent, third-party public records databases;
- properly educating and supporting its distributors, wholesalers, and retailers to ensure that they have appropriate systems in place for age verification for in-person and online sales;
- complying with local, state, and federal age restrictions for the sale of vapor products.

Attachment 4 represents a specimen of the type of advertisement and age-verification warning which VDX provides to retail store owners to emphasize the commitment to ensuring that its adult-oriented products are identified with age-restricted sales policies. I am proud of the fact that

VDX markets and sells its vaping products strictly to adult consumers.

18. VDX also included an environmental assessment for each of is menthol and menthol tobacco products in its PMTA. Attachment 5 represents a specimen of the environmental assessment which VDX submitted with its PMTA.

19. VDX did not conduct a long-term study when preparing its PMTA which compared its menthol and menthol tobacco products against its tobacco-flavored products in effecting smoking cessation because FDA's pre-PMTA materials never discussed any such requirement. Frankly, this idea of conducting a comparative efficacy test never crossed my mind because neither VDX nor any other vaping products manufacturer, have been able to market their vaping products as either smoking cessation products or less harmful from smoking (even if true) since FDA issued its Deeming Rule in 2016 because the Tobacco Control Act (TCA) and FDA's regulations specifically prohibit such comparisons and assertions. In fact, the TCA requires that a manufacturer first obtain a modified risk tobacco product order from FDA before explicitly comparing vaping products to combustible cigarettes or representing their efficacy.

20. The vaping products that were subject to VDX's PMTA and MDO generate nearly $3,000,000.00 of annual revenue and the projection of 2024 revenues based upon three quarters of sales are on track to closely match historic revenues.

21. VDX's adult-oriented products, however, are having to compete with disposable vaping products which have dominated the vaping products market since their introduction in 2020 although none of them have been granted FDA market authorization. *See* Attachment 5 which is incorporated by this reference. It has been my experience as a vape industry manufacturer that unauthorized disposable vaping products are now the predominant choice of consumers, especially consumers under 35 years of age, and that fact has reduced the overall revenues of the open-system retail sector.

22. In addition, several have adopted bans on the sale of flavored vaping products but permit VDX's menthol and menthol tobacco products, and other states have adopted laws since 2022 which created a "registry" of vaping products which bar their sale unless either authorized by FDA, still under a PMTA review, or subject to a federal court stay. VDX has been able to continue selling its menthol and vaping products in those states because FDA was still reviewing its PMTA and had not exercised enforcement discretion to force a removal of those products pending completion of the review. VDX, however, will be forced to immediately remove its menthol and menthol tobacco vaping products from those states absent a stay of the MDO.

23. VDX will lose approximately 27% of its current revenues based upon projected 2024 sales and will potentially be forced to scale back its operations and lay off employees within approximately 60 days if it does not receive a stay from the Court.

24. Pursuant to 28 U.S.C. § 1746, I verify under penalty of perjury that the factual statements in this declaration concerning myself, my activities, and my intentions are true and current.

Dated: October 25, 2024.

/s/ Ryan Chalme
RYAN CHALME

Executed in Sun Valley, California.

APPENDIX E
Excerpts from FDA Marketing Denial Order No. PM0002351

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

September 19, 2024

DENIAL

VDX Distro Inc.
Attention: Ryan Chalme, President
11152 Fleetwood Street, Suite 1
Sun Valley, CA 91352

FDA Submission Tracking Numbers (STNs): PM0002351.PD22–PM0002351.PD35, see Appendix A

Dear Ryan Chalme:

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

The statute places the burden on the applicant to make the required showing by providing that FDA "shall deny an application" for a product to receive a PMTA marketing authorization if, "upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to

such tobacco product," FDA finds that "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health" (APPH). Based on our review of your PMTAs[1], we determined that the new products, as described in your applications and specified in Appendix A, lack sufficient evidence to demonstrate that the marketing of these products is APPH. You cannot introduce or deliver for introduction these products into interstate commerce in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA. These actions may include, but are not limited to, civil money penalties, including an enhanced civil money penalty under FD&C Act section 303(f)(9)(B)(i), seizure, and/or injunction.

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

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

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

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

1. Your PMTA lacks sufficient evidence demonstrating that your flavored ENDS will provide a benefit to adult users that would be adequate to outweigh the risks to youth. There is substantial evidence that flavored ENDS, like the subject products, have significant appeal to youth and are associated with youth initiation and use. The marketing restrictions and other mitigation measures that you proposed cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. In light of the known risks to youth of marketing flavored ENDS, robust and reliable evidence is needed regarding the benefit to adult smokers, who switch completely or significantly reduce their smoking. Whether other products give adults who smoke comparable options for complete switching or significant cigarette reduction bears on the extent of the public health benefit that the subject ENDS arguably provide to that population. Because tobacco-flavored ENDS have not been shown to present the same risks to youth as flavored ENDS, marketing of flavored ENDS is APPH only if the evidence shows a benefit to adults who smoke as compared to tobacco-flavored ENDS.

This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of your flavored ENDS products over an appropriate comparator tobacco-flavored ENDS. FDA would also consider other evidence that reliably and robustly evaluated the impact of the new flavored

vs. tobacco-flavored products on switching or significant cigarette reduction over time among adults who use combustible cigarettes. We did not find such evidence in your PMTA, which did not include any studies or other evidence purporting to show that the new tobacco products provide a countervailing benefit to adult smokers. Without this information, FDA concludes that your application is insufficient to demonstrate that these products would provide an added benefit that is adequate to outweigh the risks to youth and, therefore, cannot find that permitting the marketing of your new tobacco products would be APPH. Because you have not met your burden of "showing" that permitting the marketing of the new products would be APPH as required by Section 910(c)(2)(A), we must deny authorization for your application.

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

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

not limited to, civil money penalties, seizure, and/or injunction.

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

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

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date6; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

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

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

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

If you have any questions, please contact Taylor Worsley, MPH, Regulatory Health Project Manager, at (240) 402-0047 or Taylor.Worsley@fda.hhs.gov.

Sincerely,

Digitally signed by Benjamin Apelberg -S
Date: 2024.09.19 12:59:32 -04'00'

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

APPENDIX F
RELEVANT STATUTORY PROVISIONS

21 U.S.C. § 387(1) - The term "additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

21 U.S.C. § 387a(b) - This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter. This subchapter shall also apply to any tobacco product containing nicotine that is not made or derived from tobacco.

21 U.S.C. § 387g

(a) In general

(1) Special rules

(A) Special rule for cigarettes. Beginning 3 months after June 22, 2009, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or

additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

(B) Additional special rule. Beginning 2 years after June 22, 2009, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

(2) Revision of tobacco product standards. The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (c).

(3) Tobacco product standards

(A) In general. The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

(B) Determinations

(i) Considerations. In making a finding described in subparagraph (A), the Secretary shall consider scientific evidence concerning—

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(ii) Additional considerations. In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Secretary's consideration scientific evidence that demonstrates that the proposed standard

will not reduce or eliminate the risk of illness or injury.

(4) Content of tobacco product standards. A tobacco product standard established under this section for a tobacco product—

(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

(i) for nicotine yields of the product;

(ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or

(iii) relating to any other requirement under subparagraph (B);

(B) shall, where appropriate for the protection of the public health, include—

(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii)

show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title;

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

(D) shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

* * *

(c) Proposed standards

(1) In general. The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

(2) Requirements of notice. A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

(A) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

(B) invite interested persons to submit a draft or proposed tobacco product standard for consideration by the Secretary;

(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

(D) invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard.

(d) Promulgation

(1) In general. After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a tobacco product standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

(A) if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

* * *

21 U.S.C. § 387j

(a) In general

(1) New tobacco product defined. For purposes of this section the term "new tobacco product" means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required

(A) New products. An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products. Subparagraph (A) shall not apply to a tobacco product—

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period, except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

* * *

(b) Application

(1) Contents. An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, 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;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 387g of this title which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

* * *

(c) Action on application

(1) Deadline

(A) In general. As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and

recommendation submitted under subsection (b)(2), shall—

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) Restrictions on sale and distribution. An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title.

(2) Denial of application. The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard.

(3) Denial information. Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(4) Basis for finding. For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) Basis for action

(A) Investigations. For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) Other evidence. If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.