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United States District Court, Southern District of Indiana
United States Court of Federal Claims
United States Courts of Appeals: Third, Fourth, Fifth, Sixth, Seventh, Ninth, Tenth, Eleventh and D.C. Circuits
United States Tax Court
Supreme Court of the United States

May 16, 2026

U.S. Court of Appeals for the Fifth Circuit
Attn: Lyle W. Cayce, Clerk
600 S. Maestri Place, Suite 115
New Orleans, LA 70130

**RE: *VDX Distro, Incorporated, et al. vs. FDA*, Case No. 24-60537**

Dear Mr. Cayce:

FDA's letter confirms Petitioners' arguments.

*First*, FDA's authorization of two Glas flavored products based on mandatory device-access-restriction technology is another example of it imposing a tobacco product standard outside the 21 U.S.C. § 387g notice-and-comment rulemaking requirements. It is a product standard because it concerns the product's *construction, components, and properties.* § 387g(a)(4)(B). FDA's finding that this restriction was necessary to protect public health is a generally-applicable rule, not a product-specific judgment. This is a technological floor outside the § 387g process below which no flavored product will be authorized. *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 253 (2004) ("standards" encompass both "numerical [performance] levels" and "technology with which [products] must be equipped"). This rule also "affects the rights of broad classes of unspecified individuals," *City of Arlington v. FCC*, 668

F.3d 229, 242 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013). This required notice-and-comment rulemaking and agencies cannot do through adjudication what the statute requires to be done through rulemaking. *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 764–65 (1969).

*Second*, FDA applied its check-the-box fatal flaw review of Glas's PMTA—only conducting a full scientific review because the PMTA included a comparative efficacy study. FDA has again imposed this standard outside the TCA rulemaking requirement. FDA authorizing two non-tobacco and non-menthol flavored products does not cure its *de facto* ban imposed as to all other products. Bypassing rulemaking here has real consequences: negating the opportunity to propose less burdensome alternatives; serious privacy implications of biometric surveillance go unexamined; manufacturers who relied on FDA's published guidance received no fair notice of the technology prerequisite; and the absence of an FDA evaluation of whether less restrictive measures could achieve the same public-health objective as § 387g(a)(3)(B) requires.

The question is not whether FDA has authorized *any* flavored products; but whether it has imposed a mandatory technological condition on the entire category without rulemaking. It has. The Court should recognize the Glas authorization for what it is: further evidence of an unlawful technology mandate binding all flavored ENDS manufacturers.

Respectfully,

*/s/ J. Gregory Troutman*
J. Gregory Troutman

cc: Counsel of Record (via CM/ECF and E-mail)

## CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT REQUIREMENT

This document complies with the word limit of FED. R. APP. P. 28(j), because it contains 344 words.

*/s/ J. Gregory Troutman*
J. GREGORY TROUTMAN
*Attorney for Petitioners*