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Submitted Electronically via Docket No. FDA 2013-S-0610

Robert Califf, M.D.
Commissioner of Food and Drugs U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring MD 20993

Re: Supplemental Submission to Citizen Petition
Docket No. FDA-2022-P-2483-001

Dear Commissioner:

Pursuant to 21 C.F.R. §10.30(g), please accept this supplemental submission in support of Petitioner, Vapor Vapes Inc.'s (Petitioner or Vapor Vapes), Citizen Petition filed with the U.S. Food and Drug Administration (FDA) on October 7, 2022, and assigned Docket No. **FDA-2022-P-2483-001**. The Citizen Petition was contemporaneously filed with a Petition for Stay of Administrative Action, Docket No. FDA 2022-P-2514-001; Request for Advisory Opinion, Docket No. FDA-2022-A-2732-001; and Request for Advisory Opinion, Docket No. FDA 2022-A-2740-001. Petitioner undertook these filings after it received correspondence from FDA, Center for Tobacco Products (CTP) dated September 9, 2022, which related to Warning Letter Number ER2200479, dated March 30. 2022. The Warning Letter advised Vapor Vapes that its tobacco products were adulterated and misbranded, and CTP's later correspondence advised Petitioner that it "ha[d] not adequately addressed the violations identified in the Warning

Letter."[1] Due to Petitioner's concerns about potential enforcement action and its inability to achieve a collaborative forward plan with CTP despite its best efforts, the filings were a necessary means to gain the requested guidance and direction for compliance.

Regarding the Citizen Petition, Vapor Vapes asserted, and continues to urge here, that its tobacco products are not subject to enforcement because they are manufactured for export, which the law, 21 U.S.C. 381(e)(1), expressly excludes from this type of oversight. Petitioner believed that as long as it abided by the words contained in applicable law and accompanying regulation, 21 CFR §101.(b), it was compliant. Yet, despite this reliance, inspection determined otherwise and Vapor Vapes is in an information vacuum as it strives to stay in business.

The purpose of this supplemental submission is to ask the FDA to take official notice of the United States Court of Appeals for the Fifth Circuit Court *en banc* decision issued in the consolidated appeals, *Wages & White Lion Invs., L.L.C. v. Food & Drug Admin.*, 90 F.4th 357 (*en banc*) (5th Cir. 2024). There, the Court set aside the FDA's marketing denial orders and remanded the matters to FDA for "a full and fair regulatory proceeding."[2] The majority opinion is helpful here because it took a deep dive into the manner in which FDA communicated policy and administered its review process, finding that the adjudicated process fell short of due process because the reviews did not accord with longstanding review practice and petitioners' reasonable interpretation of and reliance upon existing FDA policy, guidance, and communications. A copy of the Fifth Circuit's decision is included with this supplemental submission.

The Court's holding is notable to Petitioner based upon three (3) of the Fifth Circuit's bases for remand: the fair notice doctrine; the FDA's apparent change in position without

[1] *Re: Warning Letter Reply Reference Number ER2200479* authored by CDR Collins Mason, Acting Director, Division of Enforcement and Manufacturing, CTP (September 9, 2022).
[2] 90 F.4th at 363.

acknowledging and explaining the change; and notwithstanding some agency explanation of change, a party cannot be faulted for good faith reliance on the agency's prior position.

The Fair Notice Doctrine entitles Vapor Vapes to be Adequately Apprised that FDA's Enforcement Policy and Inspection Practice Now Includes Finding Tobacco Products for Export to be Misbranded and Adulterated and Petitioner's Reasonable Expectation of, and Reliance on Receipt of Same, is Justifiable.

The Fifth Circuit opined that the fair notice doctrine "requires administrative agencies to give the public fair notice of their rules before finding a violation of them."[3]

Petitioner has been conducting business and operating, predictably and reasonably, in good faith reliance upon the clear statutory language excluding exports that is contained in 21 U.S.C. 381(e)(1):

> A food, drug, device, tobacco product or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this chapter, and a tobacco product intended for export shall not be deemed to be in violation of section 387f(e), 387g, 387k, or 387t(a) of this title, if it –
>
> (A) accords to the specifications of the foreign purchaser,
>
> (B) is not in conflict with the laws of the country to which it is intended for export,
>
> (C) is labeled on the outside of the shipping package that it is intended for export, and
>
> (D) is not sold or offered for sale in domestic commerce.
>
> [Emphasis added.]

As Petitioner states in the Citizen Petition, it construed the law and regulations concerning tobacco products for export in the absence of substantive guidance — but the statute's clear wording governs in only one direction.

Generally, CTP's printed guidance says:

[3] *Wages & White Lion*, 90 F.4th 357, 374 (*en banc*) (5th Cir. 2024).

> FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.[4]
>
> [Emphasis added.]

Notwithstanding "specific" and plain statutory language in this context, FDA's inspection deemed Petitioner's products misbranded and adulterated. FDA's statutory construction in the realm of Petitioner's products is contrary to the statute's precise wording.

The FDA's action in this regard, without fairly apprising Petitioner that it intends to not enforce the law as written, leaves Petitioner in the precarious situation of holding goods that it believed were produced lawfully, but which suddenly, and without notice, are non-compliant and could subject Petitioner to penalty and forfeiture.

FDA's Current Enforcement Strategy Appears to be a Change in Position Without Explanation.

The Fifth Circuit highlighted the core problem here — that an agency "…may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books."[5]

Petitioner is placed in an untenable situation which the Fifth Circuit ruled was more than the law required. That is, in order to be compliant with the Federal Food, Drug & Cosmetic Act and FDA enforcement policy, Petitioner would need to "exercise…extraordinary intuition or

[4] *See e.g., Guidance for Industry, Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products (Revised)*, Small Entity Compliance Guide (March 2023). Vapor Vapes reiterates what it points to in the Citizen Petition at p. 2: a Guidance document, though non-binding, will present the views of the Secretary on matters under the jurisdiction of the FDA, and shall ensure that FDA employees "do not deviate from such guidances without appropriate justification and supervisory occurrence" (*quoting* 21 U.S.C. §371(h)(1)(A)-(B)).

[5] *Wages & White Lion*, 90 F.4th at 381 *quoting FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515, 129 S.Ct. 1800, 173 L.Ed.2d 738 (2009).

[have] the aid of a psychic"[6] to discern FDA's enforcement position that it's goods were misbranded and adulterated, when it manufactured and offered the goods for sale in good faith and reasonable reliance on express statutory language that patently excludes products for export from FDA misbranding and adulterated product purview.

Petitioner's holding pattern is not sustainable in the context of potential enforcement activity. It undertook a plan to address the Warning Letter, but the effort was rebuffed. While providing Vapor Vapes with insubstantial feedback — that its remediation efforts were simply "inadequate" without explanation — FDA remains unwilling to provide requested guidance and direction.[7] The Fifth Circuit characterized FDA's lack of responsiveness to the parties' requests:

> Immediately after receiving the new scientific-studies-or-bust requirement in the August 2021 press release, petitioners asked FDA for time to perform the newly required studies. Without acknowledging that request, on September 14 and 16, 2021, FDA issued marketing denial orders ("MDOs") to Triton and Vapetasia, finding that their PMTAs failed to include the once-optional-but-now-required scientific studies.[8]

By analogy, much the same is happening in Petitioner's matter. Efforts to reach out and understand are not reciprocal. The Fifth Circuit believed the lack of communication was unwarranted and contributed to a remand ruling. Petitioner submits that a measure of fairness should be allocated to its efforts and longstanding good faith toward compliance.

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[6] 90 F.4th at 376.
[7] *Consider e.g.*, "We [CTP] cannot provide any kind of advice or consulting – therefore, nothing we say should be construed as such," [from contemporaneous remote meeting notes, Clark-Esposito Law Firm, P.C. (August 10, 2022)].
[8] 90 F.4th at 370.

For the foregoing reasons, Petitioner respectfully requests that the FDA note the findings and reasoning of the Fifth Circuit and apply those principles to the matter at hand in granting the relief requested in the Citizen Petition.[9]

I may be reached via email at Deanna@clarkespositolaw.com or 917-546-6997. Thank you.

Respectfully,

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Encl. *Wages & White Lion Invs., L.L.C. v. Food & Drug Admin.*, 90 F.4th 357 (*en banc*) (5th Cir. 2024)

[9] Petitioner requested at p. 5:

> …issuance of a Guidance document and an update to the IOM that legally establishes parameters that (1) a manufacturer can follow and implement to ensure compliance with the FD&C Act, and (2) that an FDA inspector can follow to objectively evaluate a manufacturer.