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October 7, 2022

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

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

Re: Petition for Stay of Administrative Action

To Whom It May Concern:

The undersigned submits this Petition for Stay of Administrative Action, pursuant to 21 CFR §10.35, requesting that the Commissioner of Food and Drugs stay the effective date of September 9, 2022,[1] recorded under the U.S. Food and Drug Administration (FDA), Center for Tobacco Products (CTP) Warning Letter number **ER2200479**,[2] issued to Vapor Vapes, Inc. (hereinafter, *Petitioner*).

A. Decision Involved

Under original Warning Letter ER2200479, FDA's Center for Tobacco Products (CTP) Office of Compliance and Enforcement alleged that certain products of Petitioner were potentially misbranded under section 903(a)(6) of the Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 387c(a)(6)) and adulterated under subsection 902(6)(A) of the FD&C Act (21 U.S.C. § 387b(6)(A).

Following issuance of this original Warning Letter, the Petitioner, through its undersigned counsel, met with CTP on August 10, 2022 and thereafter provided a timely initial response dated August 24, 2022, which contained a detailed plan of corrective action for addressing CTP concerns regarding Petitioner's products, including the reasonable timelines anticipated for accomplishing the proposed plan of corrective action.[3] In addition to the proposed plan of corrective action, Petitioner posed to CTP several points for clarification where applicable FDA regulation remains either silent, or unclear, as to Petitioner's compliance obligations given its particular lines of business, and, outlined specific elements of its lines of business which fall beyond the scope

[1] This is the stated date upon which CTP has advised that it intends to abandon further collaborative and corrective efforts, and to commence inspection and enforcement activity in its letter dated September 9, 2022: CDR Collins Mason, Acting Director, Division of Enforcement and Manufacturing, CTP, *Re Warning Letter Reply Reference Number ER2200479* (September 9, 2022) p.2 para.5.
[2] FDA's Center for Tobacco Products (CTP) issued this original Warning Letter recorded under ER2200479 on March 30, 2022.
[3] A detailed procedural history may be found in CTP correspondence from CDR Collins Mason, Acting Director, Division of Enforcement and Manufacturing, CTP, *Re Warning Letter Reply Reference Number ER2200479* (September 9, 2022) pp.1-2.

of CTP's misbranding and adulteration enforcement authority (these points are restated in greater detail at Section C, below).[4]

Notwithstanding the timely submitted proposed plan of Petitioner's corrective action, the above points were submitted to CTP for clarification, and included details of such portions of Petitioner's lines of business which fall beyond the scope of CTP's misbranding and adulteration enforcement authority

In response to such plan, in its letter dated September 9, 2022, CTP asserted simply that "it **appears** that your proposed actions to address any violations and bring your products into compliance do not fully address the issues identified in the Warning Letter, and/or if fully implemented, would not prevent any similar or future violations of the FD&C Act."[5] Petitioner subsequently submitted updates regarding the progress of corrective actions being implemented in a letter September 9, 2022, for which no response, not even an acknowledgement of receipt has been received.

Petitioner disagrees with the original assessment, it also cannot be denied that the assessment disregards in full, both the proposed plan of corrective action, the valid points submitted for clarification, and those lines of business falling beyond the scope of CTP's misbranding and adulteration enforcement authority. As such, Petitioner respectfully submits that a Stay of Administrative Action is appropriate pending an authoritative resolution of the outstanding matters (restated in greater detail in Section C, below).

B. Action Requested

In response to CTP's Office of Compliance and Enforcement's most recent correspondence dated September 9, 2022, and pursuant to 21 CFR § 10.35, Petitioner respectfully petitions for a Stay of Administrative Action, to include, but not limited to, further inspection, enforcement, and regulatory action as contemplated by CTP in its September 9, 2022, correspondence,[6] pending a determination of Petitioner's Citizen's Petition, temporarily assigned Docket # 2013-S-0610, filed on October 6, 2022.[7] The Stay of Administrative Action is requested to commence immediately and to continue during and throughout the pendency of a decision on the Citizen's Petition which is related to the outstanding matters detailed herein and which a true copy is attached to this petition for reference.[8] The Citizen's Petition has been prepared in an effort to specifically address and resolve certain of these matters stated herein, as well as those identified as a line of business falling outside of CTP's misbranding and adulteration enforcement authority.

C. Statement of Grounds

[4] These points of clarification and specific elements of Petitioner's lines of business falling outside CTP's misbranding and adulteration enforcement authority were detailed, *inter alia*, in letters from the Petitioner and its counsel dated May 19, 2022, and August 24, 2022.

[5] CDR Colllins Mason, Acting Director, Division of Enforcement and Manufacturing, CTP, *Re Warning Letter Reply Reference Number ER2200479* (September 9, 2022) p.2, para.2 [emphasis added].

[6] Reading in relevant part, "FDA will periodically inspect your establishment to assess your compliance with applicable federal laws and regulations" and "Failure to address any violations of the regulations in 21 C.F.R. Parts 1140, 1141, and 1143, may lead to regulatory action, including, but not limited to, civil money penalties, seizure, and/or injunction.": CDR Collins Mason, Acting Director, Division of Enforcement and Manufacturing, CTP, *Re Warning Letter Reply Reference Number ER2200479* (September 9, 2022) p.2, para.5.

[7] A unique docket number for Petitioner's Citizen Petition has not yet been received from FDA's Dockets Management, however, unique comment tracking number I8x-h9wa-4lpq was assigned on October 6, 2022.

[8] Citizen's Petition dated October 6, 2022.

This Petition for a Stay of Administrative Action is supported by each of the bases as outlined below.

First, clarification is required as to CTP's understanding of, and approach to, e-liquids and other components and parts of deemed tobacco products which are sold or distributed *only* for further manufacturing. Petitioner has been operating in predictable reliance upon the originally published Deeming Rule in which FDA stated that it did not intend to enforce the premarket authorization requirement against such products, as they *do not* constitute a finished tobacco product.[9]

To the extent that CTP has inferred from Petitioner's website that such unfinished products as those described above are conceivably accessible to consumers for immediate use in their unfinished state, Petitioner has since responded as a part of its plan of corrective action that it intends to implement significant barriers within its website to ensure sales are made only to verified wholesalers for further manufacturing.[10]

Second, a substantial proportion of Petitioner's business falls beyond the scope of CTP's misbranding and adulteration enforcement authority, namely: Petitioner manufactures products for export which are statutorily exempt from CTP's misbranding and adulteration enforcement authority.[11] To this end, Petitioner has proposed to CTP in its plan of corrective action to physically segregate a section of its warehouse space to house products destined for export.[12]

Third, in addition to export operations, Petitioner manufactures products which *do not* contain nicotine and are *not intended* for any subsequent use in or with a covered tobacco product (*i.e.*, flavor products). In an effort to resolve CTP allegations of misbranding and adulteration with regard to such products, Petitioner in its proposed plan of corrective action advised CTP of its intention to clearly distinguish such products by removing the Nicotine Warning Statement from such product labels, and to segregate these lines of business.

Further, and importantly, with regard to points one, two, and three immediately above, in a remote follow-up meeting and correspondence with CTP, the Petitioner repeatedly requested both clarification and guidance from CTP as to how it may augment its unfinished products operations and export operations to resolve any subsisting concerns of CTP.[13] On each occasion CTP declined to comment upon, or to offer clarification or guidance on these points.[14]

It is the position of the Petitioner that FDA and its CTP are seeking to foreclose Petitioner's ability to conduct lawful business on the subjective premise that some portion, or portions, of its operations are allegedly

[9] 81 FR 28974, 28995 (May 10, 2016): *see*, Response to Comment 26, "[A]n e-liquid that is sold or distributed for further manufacturing into a finished ENDS product is not itself a finished tobacco product."
[10] Outlined in correspondence from the Clark-Esposito Law Firm, P.C. (counsel to Petitioner) to CTP, dated August 24, 2022 (at p.4) *and* September 20, 2022 (at p.1).
[11] Pursuant to 21 U.S.C. § 381e(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."
[12] Outlined in correspondence from the Clark-Esposito Law Firm, P.C. to CTP, dated August 24, 2022 (at pp.3-4) *and* September 20, 2022 (at p.2).
[13] A teleconference was held with CTP on August 10, 2022, followed by related correspondence between the Clark-Esposito Law Firm, P.C. and CTP on August 11, August 29, and September 9, 2022.
[14] *Consider, e.g.*, "We [CTP] cannot provide any kind of advice or consulting – therefore, nothing we say should be construed as such", from contemporaneous meeting notes, Clark-Esposito Law Firm, P.C. (August 11, 2022).

violative, and further, CTP has disregarded Petitioner's significant good faith efforts to resolve the agency's concerns pertaining to its FDA regulated operations through its proposed plan of corrective action. Petitioner respectfully submits that it would be improper to allow the agency to exercise such expansive enforcement authority for 1) readily remediable alleged violations within its regulated lines of business, 2) operations for which FDA has failed to publish clear and actionable rules, and/or for which FDA has since disavowed its previously published position and upon which Petitioner has acted in reliance (unfinished tobacco products destined for further manufacturing), and 3) operations which are statutorily excluded from FDA's misbranding and adulteration enforcement authority (products destined for export, and domestic products containing no nicotine which are not intended for use in or with a covered tobacco product).

I may be reached via email at Deanna@clarkespositolaw.com or 917-546-6997 for further information or follow-up to this petition. Thank you.

Respectfully,

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Encl. Citizen's Petition