IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
BLUEFIELD DIVISION

UNITED STATES OF AMERICA Plaintiff, v. SOUL VAPOR, LLC, a corporation, and AURELIUS JEFFREY, an individual, Defendants.	Civil No. 1:22-cv-00458 **COMPLAINT FOR PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin Soul Vapor, LLC ("Soul Vapor"), a corporation, and Aurelius Jeffrey, an individual from violating:

A. 21 U.S.C. § 331(k), by causing tobacco products, within the meaning of 21 U.S.C. § 321(rr), to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce; and

B. 21 U.S.C. § 331(q)(2), by submitting information required by or under the Act respecting a tobacco product that is and false or misleading in any material respect.

Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a), and personal jurisdiction over all parties.

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

Defendants

4. Defendant Soul Vapor is a West Virginia corporation located at 604 Thorn Street, Princeton, WV, 24740-3757 ("Defendants' establishment"), within the jurisdiction of this court.

5. Defendant Aurelius Jeffrey is Soul Vapor's sole owner, and the most responsible individual at Soul Vapor. He oversees all business aspects for Soul Vapor, makes all business decisions for Soul Vapor, and performs his duties at Defendants' establishment, within the jurisdiction of this Court.

Defendants' Operations

6. Defendants manufacture finished electronic nicotine delivery system ("ENDS") products, including finished ENDS products under the Soul Vapor brand, at Defendants' establishment. Defendants' manufacturing activities include mixing, bottling, and labeling their ENDS products. From Defendants' establishment, Defendants also sell and distribute their ENDS products, and ENDS products manufactured by others, to individuals for personal consumption.

Defendants' ENDS Products Are Adulterated and Misbranded

7. Defendants violate the Act by causing tobacco products to become adulterated or misbranded while they are held for sale after shipment of one or more of their components in interstate commerce. 21 U.S.C. § 331(k).

Defendants' ENDS Products Are Tobacco Products

8. The Act defines "tobacco product" at 21 U.S.C. § 321(rr) to include "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product." This definition includes "component[s]" and "part[s]," which FDA regulations, in turn, define as "any software or assembly of materials intended or reasonably expected: . . . [t]o alter or affect the tobacco product's performance, composition, constituents, or characteristics; or . . . [t]o be used with or for the human consumption of a tobacco product." 21 C.F.R. §§ 1100.3, 1107.12, 1114.3, 1140.3. A "tobacco product" within the meaning of 21 U.S.C. § 321(rr) is generally subject to the requirements in 21 U.S.C. Chapter 9, Subchapter IX. *See* 21 U.S.C. § 387a(b) (providing that such subchapter shall apply to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that [FDA] by regulation deems to be subject to this subchapter"); 81 Fed. Reg. 28974, 28975 (May 10, 2016) (deeming all products meeting the definition of "tobacco product" at 21 U.S.C. § 321(rr), except accessories of such newly deemed products, to be subject to such subchapter).

9. ENDS products generally meet the definition of "tobacco product" at 21 U.S.C. § 321(rr), and include: "devices, components, and/or parts that deliver aerosolized e-liquid when inhaled." FDA, *Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)** (Apr. 2020), 9–10, https://go.usa.gov/xuvn5. E-liquids "are a type of ENDS product and generally refer to liquid nicotine and nicotine-containing e-liquids (i.e., liquid nicotine combined with colorings, flavorings, and/or other ingredients)." *Id.* E-liquids that are not made or derived from tobacco and that do not contain nicotine from any source may still meet the

definition of "tobacco product" at 21 U.S.C. § 321(rr) as a "component" or "part." *See* 81 Fed. Reg. 28974, 29041 (May 10, 2016).

10. Defendants' ENDS products consist of liquid nicotine at varying concentrations ("nicotine liquids") and blends of vegetable glycerin, propylene glycol, and flavorings ("VG/PG/flavoring blends"). Defendants' nicotine liquids are made or derived from tobacco, or contain nicotine from any source, and are intended for human consumption, and thus are "tobacco product[s]" within the meaning of 21 U.S.C. § 321(rr). Defendants' VG/PG/flavoring blends are intended or reasonably expected to be mixed with a nicotine liquid—i.e., a tobacco product—and thus to alter or affect the tobacco product's performance, composition, constituents, or characteristics, and to be used with or for the human consumption of a tobacco product. Accordingly, Defendants' VG/PG/flavoring blends are "component[s]" or "part[s]" within the meaning of 21 C.F.R. §§ 1100.3, 1107.12, 1114.3, 1140.3, and thus "tobacco product[s]" within the meaning of 21 U.S.C. § 321(rr).

Defendants' ENDS Products Are New Tobacco Products

11. The Act defines "new tobacco product" at 21 U.S.C. § 387j(a)(1) to include "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007."

12. Defendants' ENDS products were not commercially marketed in the United States as of February 15, 2007, and thus are "new tobacco product[s]" within the meaning of 21 U.S.C. § 387j(a)(1).

Pathways to Market for New Tobacco Products

13. A new tobacco product may receive FDA marketing authorization through any one of three pathways: (1) the premarket tobacco product application ("PMTA") pathway under

21 U.S.C. § 387j, through which FDA reviews a PMTA and issues a marketing granted order for the new tobacco product ("MGO") under 21 U.S.C. § 387j(c)(1)(A)(i) upon a finding that the product is appropriate for the protection of the public health; (2) the substantial equivalence ("SE") pathway under 21 U.S.C. § 387j(a)(2)(A)(i), through which FDA reviews a report submitted under 21 U.S.C. § 387e(j) ("SE report") for the product and issues an order determining, among other things, that it is substantially equivalent to a tobacco product commercially marketed in the U.S. as of February 15, 2007, or a tobacco product marketed after that date, but which FDA previously determined to be substantially equivalent ("SE order"); or (3) the SE exemption pathway under 21 U.S.C. § 387j(a)(2)(A)(ii), through which FDA reviews an exemption request submitted under 21 C.F.R. § 1107.1 and a report submitted under 21 U.S.C. § 387e(j)(1) ("abbreviated report") for the product, and issues a "found-exempt" order pursuant to 21 U.S.C. § 387e(j)(3)(A).

14. A new tobacco product that is required by 21 U.S.C. § 387j(a) to have premarket review and does not have an MGO in effect under 21 U.S.C. § 387j(c)(1)(A)(i), is adulterated under 21 U.S.C. § 387b(6)(A). A new tobacco product is required by 21 U.S.C. § 387j(a) to have premarket review, unless it has a SE order or found-exempt order in effect. *See* 21 U.S.C. § 387j(a)(2)(A).

15. A new tobacco product for which a "notice or other information respecting it was not provided as required" under the SE or SE exemption pathway, including a SE report or an abbreviated report, is misbranded under 21 U.S.C. § 387c(a)(6).

Defendants' ENDS Products Have Not Been Authorized by FDA and Are Both Adulterated and Misbranded

16. Defendants' ENDS products, as "new tobacco product[s]" within the meaning of 21 U.S.C. § 387j(a)(1), are required by 21 U.S.C. § 387j(a) to have premarket review, as they do not have a SE order or found-exempt order in effect. Defendants' ENDS products do not have an MGO in effect under 21 U.S.C. § 387j(c)(1)(A)(i). Accordingly, Defendants' ENDS products are adulterated under 21 U.S.C. § 387b(6)(A).

17. In addition, neither a SE report nor an abbreviated report has been submitted for any of Defendants' ENDS products. Accordingly, Defendants' ENDS products are misbranded under 21 U.S.C. § 387c(a)(6).

Defendants Engage in Interstate Commerce

18. Defendants hold their ENDS products for sale after shipment of their components in interstate commerce. Specifically, the nicotine that Defendants use to make their nicotine liquids comes from California and Arizona, and the vegetable glycerin and propylene glycol that Defendants use to make their VG/PG/flavoring blends come from Ohio.

Defendants Submitted Required Tobacco Product Information That Was Materially False

19. The Act prohibits the submission of information required by or under the Act respecting a tobacco product that is false or misleading in any material respect. 21 U.S.C. § 331(q)(2).

20. Any person who owns or operates an establishment engaged in the manufacture of tobacco products must annually register with FDA the name, place of business, and all such establishments of that person. 21 U.S.C. § 387e(b).

21. Defendants own and operate their establishment and engage in the manufacture of tobacco products from such location. Accordingly, as required under the Act, Defendants must

annually register with FDA their name, place of business, and all their establishments. *See* 21 U.S.C. § 387e(b).

22. Consistent with such requirement, on September 20, 2021, Defendants submitted an establishment registration to FDA. However, in such registration, Defendants changed the activity status for their establishment from "active" to "inactive," and reported, as a reason, that the establishment was "[o]ut of business." Because Defendants were engaged in the manufacture of tobacco products from such establishment at that time (through, e.g., mixing, bottling, and labeling finished ENDS products), such information was materially false. By submitting a required establishment registration with materially false information, Defendants violate the Act, 21 U.S.C. § 331(q)(2).

Defendants' History of Violative Conduct

23. Defendants are aware that their practices violate the Act. FDA has warned Defendants about their violative conduct and explained that continued violations could lead to enforcement action, including an injunction.

24. FDA sent Defendants a Warning Letter on May 21, 2021, after conducting a review of Soul Vapor's website. The Warning Letter informed Defendants that they manufacture and offer for sale or distribution new tobacco products that lack required FDA authorization, including certain finished ENDS products under the Soul Vapor brand. The Warning Letter further cautioned that such products are adulterated under 21 U.S.C. § 387b(6)(A) and misbranded under 21 U.S.C. § 387c(a)(6), and that Defendants' failure to address their violations of the Act relating to tobacco products could lead to enforcement action, including an injunction.

25. On June 8, 2021, FDA held a teleconference with Defendant Jeffrey, to answer any questions regarding the violations cited in the Warning Letter. During the teleconference, Defendant Jeffrey stated that, to address such violations, he would discontinue manufacturing and selling Soul Vapor-brand ENDS products and place all remaining Soul Vapor-brand inventory in storage until they receive FDA authorization. In an email sent to FDA on that same day, Defendant Jeffrey added that he would remove the payment gateway from the Soul Vapor website.

26. On July 20, 2021, after observing that Defendants' website still offered for sale or distribution new tobacco products that lack required FDA authorization, FDA held a follow-up teleconference with Defendant Jeffrey. During the teleconference, Defendant Jeffrey indicated he would modify the Soul Vapor website to state that Soul Vapor's e-liquid products are no longer for sale. In an email sent to FDA on that same day, Defendant Jeffrey added that Defendants' "ejuice is no longer being manufactured [and] is no longer available for purchase."

27. FDA inspected Defendants' establishment between March 23 and 25, 2022. During this inspection, FDA investigators observed that, contrary to Defendant Jeffrey's statements during the June 8 and July 20, 2021 teleconferences, Defendants continued to manufacture, sell, and distribute new tobacco products, including finished e-liquid products under the Soul Vapor brand, that lacked required FDA authorization, in violation of the Act. At the close of the inspection, FDA investigators reminded Defendant Jeffrey of his responsibility to ensure compliance with the Act. Defendant Jeffrey did not promise any corrective actions that would resolve these violations during the inspection, and has not contacted FDA since then.

Request for Relief

28. Despite prior notifications, Defendants remain unable or unwilling to comply with the Act. Unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(k), by causing tobacco products to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce; and

B. Violating 21 U.S.C. § 331(q)(2), by submitting information required by or under the Act respecting any tobacco product that is false or misleading in any material respect.

II. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business, and all records relating to the manufacture, sale, and distribution of tobacco products, to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

III. Award Plaintiff its costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

Dated: October 18, 2022

Respectfully submitted,

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