[Type text]

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

UNITED STATES OF AMERICA Plaintiff, v. VAPOR CRAFT LLC, a limited liability company, and MELISSA D. ANDERSON, an individual, Defendants.	Civil No. _____ **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 Vapor Craft LLC ("Vapor Craft" or "the company"), a limited liability company, and Melissa D. Anderson (collectively, "Defendants") from violating 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.

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 Vapor Craft is a Georgia limited liability company with a registered office address at 6100 Veterans Pkwy., Ste 6, Columbus, GA 31909, within the jurisdiction of this Court. The company conducts its tobacco product operations from this location.

5. Defendant Melissa D. Anderson is Vapor Craft's owner and the most responsible individual at the company. Defendant Anderson oversees all aspects of the company's operations, including raw ingredient purchasing, formula mixing, and product packaging and labeling.

Defendants' Operations

6. Defendants manufacture finished electronic nicotine delivery system ("ENDS") products, including finished e-liquids under the Vapor Craft brand (hereinafter, "Defendants' ENDS products" or "their ENDS products"). Defendants' manufacturing activities include mixing, bottling, and labeling their ENDS products. Defendants sell their ENDS products to individuals for personal consumption.

Defendants' ENDS Products Are Adulterated and Misbranded

7. Defendants violate the Act 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. 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." 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.*

10. Defendants' ENDS products 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' 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 an order permitting marketing of 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 United States 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 an 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 an 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 an 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 an 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 flavors that Defendants use to make their ENDS products come from California and the nicotine comes from Arizona.

Defendants' History of Violative Conduct

19. 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.

20. An FDA inspection conducted at Defendants' facility between July 16 and 19, 2021, revealed that the company was manufacturing and offering for sale new tobacco products that lacked the required FDA authorization.

21. FDA sent the company and Defendant Anderson a Warning Letter on August 26, 2021, informing them that they manufacture and offer for sale or distribution new tobacco

products that lack required FDA authorization. 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 their failure to address their violations of the Act relating to tobacco products could lead to enforcement action, including an injunction. The Warning Letter requested a written response be submitted to FDA within 15 business days.

22. Defendants Vapor Craft and Anderson did not respond to the Warning Letter. FDA then sent Defendants an Inadequate Response Letter, instructing them to take prompt action to address their violations and again reminding them that their failure to address violations could lead to enforcement action. FDA received no response to the Inadequate Response Letter.

23. On March 29 and 30, 2022, FDA conducted a follow-up inspection at Defendants' facility and found that Defendants continue to manufacture, sell, and distribute new tobacco products that lack required FDA authorization, in violation of the Act. FDA investigators discussed these violations with Defendant Anderson and reminded her of her responsibility to ensure compliance with the Act. Defendant Anderson did not promise any corrective actions that would resolve these violations, and Defendants have not contacted FDA since then.

Request for Relief

24. 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 doing

or causing a violation of 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;

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.

Respectfully submitted,

PETER D. LEARY
United States Attorney

/s/ Todd P. Swanson
TODD P. SWANSON
Ga. Bar No. 496989
W. TAYLOR McNEILL
Ga. Bar No. 239540
Assistant United States Attorneys
United States Attorney's Office
Middle District of Georgia
P.O. Box 1702
Macon, GA 31202
(478) 621-2728
todd.swanson@usdoj.gov

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director
Consumer Protection Branch

/s/ Christina Parascandola
CHRISTINA PARASCANDOLA
Senior Litigation Counsel
District of Columbia Bar No. 468479
JOSHUA BROWNING
Trial Attorney
District of Columbia Bar No. 1510857
Consumer Protection Branch
United States Department of Justice
Civil Division, 6th Floor South
Washington, DC 20001
(202) 514-3097
christina.parascandola@usdoj.gov

Of counsel:

MARK RAZA
Chief Counsel
United States Food and Drug
Administration

PERHAM GORJI
Deputy Chief Counsel for Litigation

JONATHAN SILBERMAN
Associate Chief Counsel for Enforcement
United States Department of
Health and Human Services
Office of the General Counsel
Food and Drug Division
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002