IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

UNITED STATES OF AMERICA Plaintiff, v. LUCKY'S CONVENIENCE & TOBACCO, LLC, d/b/a LUCKY'S VAPE & SMOKE SHOP, a limited liability company, and KEVIN H. NGUYEN, and THOMAS B. ROGERS, individuals, Defendants.	Civil No. 22-1237 **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 Lucky's Convenience & Tobacco, LLC, d/b/a Lucky's Vape & Smoke ("Lucky's"), a limited liability company, and Kevin H. Nguyen, and Thomas B. Rogers, individuals, 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 Lucky's is a Kansas limited liability company with three retail locations within the jurisdiction of this court: (1) 4100 E. Harry Street, Suite 35, Wichita, KS 67218 ("Main Facility"); (2) 120 N. West Street, Suite 10, Wichita, KS 67203 ("West Street Facility"); and (3) 7926 E. Harry Street, Wichita, KS 67207.

5. Defendant Nguyen owns approximately 45% of Lucky's. He is responsible for the company's day-to-day operations at all three facilities, including manufacturing, inventory, quality control, and retail operations.

6. Defendant Rogers owns approximately 45% of Lucky's. He is responsible for the company's accounting, finances, and other managing duties, as well as communicating with FDA and the company's FDA registration and product listing.

Defendants' Operations

7. Defendants manufacture finished electronic nicotine delivery system ("ENDS") products, including finished e-liquids, at their three retail locations. At these locations, Defendants' manufacturing activities include mixing, bottling, and labeling their ENDS products, and Defendants also sell and distribute their ENDS products to individuals for personal consumption.

Defendants' ENDS Products Are Adulterated and Misbranded

8. 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

9. 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).

10. ENDS products 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)

11. Defendants' ENDS products consist of vegetable glycerin ("VG") alone, propylene glycol ("PG") alone, flavors alone, VG mixed with liquid nicotine at varying concentrations ("VG/nicotine blends"), and PG mixed with flavor(s) ("PG/flavor blends"). Defendants' VG/nicotine blends 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 often sell VG, PG, and flavors with empty bottles and tubes of prepacked nicotine (manufactured and packaged by a third-party company), with the individual products to be mixed by the customer off-site. Defendants' VG, PG, flavors, and PG/flavor blends are intended or reasonably expected to be mixed with liquid nicotine—*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, these products 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

12. 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."

13. 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

14. A new tobacco product may receive FDA marketing authorization through anyone 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 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).

15. A new tobacco product that is required by 21 U.S.C. § 387j(a) to have premarket review and does not have a 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).

16. 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

17. 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 a 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).

18. 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

19. Defendants hold their ENDS products for sale after shipment of their components in interstate commerce. Specifically, the nicotine that Defendants use to make their VG/nicotine blends comes from Oklahoma; the flavors that Defendants use in their custom/single flavors and PG/flavor blends come from New Mexico, Oklahoma, and California; the PG that Defendants use in their PG/flavor blends and rebottled/relabeled PG come from Utah, Michigan, and Georgia; and the VG that Defendants use in their VG/nicotine blends and rebottled/relabeled VG come from Utah, Michigan, and Georgia.

Defendants' History of Violative Conduct

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

21. An FDA inspection conducted on March 23, 2021, at the West Street Facility revealed that Lucky's was manufacturing and offering for sale new tobacco products that lacked the required FDA authorization.

22. On April 16, 2021, FDA sent a Warning Letter to Lucky's and Defendant Rogers, informing them that FDA had determined that they manufacture and offer for sale or distribution new tobacco products that lack required FDA authorization, specifically Lucky's Vape e-liquid products. 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 the failure to address their violations of the Act relating to tobacco products could lead to enforcement action, including an injunction.

23. On June 8, 2021, FDA held a teleconference with Defendant Rogers. During the teleconference, Defendant Rogers stated that Lucky's had ceased all manufacturing of finished e-liquid products prior to May 1, 2021. FDA requested that Defendant Rogers submit a written response to memorialize Lucky's corrective actions.

24. FDA followed up on its request for a written response regarding corrective actions through emails to Defendant Rogers on June 10, 2021, and June 24, 2021, and by letter on July 2, 2021. In each communication, FDA stated that the company had not addressed its violations referenced in the Warning Letter and repeated that failure to address these violations may result in enforcement action, including an injunction. Defendants never responded to these communications.

25. FDA inspected Defendants' West Street Facility from March 29-30, 2022, and the Main Facility from March 30–April 1, 2022 ("March/April 2022 inspection"). FDA investigators observed that Defendants continued to manufacture, sell, and distribute new

tobacco products, including finished e-liquid products that lacked required FDA authorization, in violation of the Act.

26. At the close of the March/April 2022 inspection of the West Street Facility and Main Facility, FDA investigators discussed these violations with Defendant Nguyen. Specifically, FDA investigators advised that the failure to resolve these violations could result in FDA pursuing enforcement action, including injunction. Defendant Nguyen stated he would need to further discuss the issues with Defendant Rogers before making any decision about a corrective action. Defendants have not contacted FDA since then.

Request for Relief

27. Despite numerous warnings, Defendants remain 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.

Place of Trial

Pursuant to D. Kan R. 40.2, Plaintiff requests that trial be held in Wichita, Kansas

Dated: October 18, 2022

Respectfully submitted,

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