UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

UNITED STATES OF AMERICA, Plaintiff, v. JESSICA M. FITZGERALD a/k/a JESSICA FORIT and MICHELLE L. ALLEN a/k/a MICHELLE WINDEMULLER-ALLEN, individually, and collectively d/b/a VAPE JUNKIE EJUICE, Defendants.	Civil No. 2:23-cv-01130-SPC-KCD **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction against Jessica Fitzgerald a/k/a Jessica Forit and Michelle L. Allen a/k/a Michelle Windemuller-Allen, individually, and collectively d/b/a Vape Junkie Ejuice ("Vape Junkie Ejuice" or the "firm") (collectively, "Defendants"), and Defendant Fitzgerald having appeared and consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over the parties executing this consent decree of permanent injunction.

2. The Complaint states a cause of action against Defendant Fitzgerald under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. (the "Act").

3. The complaint alleges that Defendant Fitzgerald violates 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, tobacco products, within the meaning of 21 U.S.C § 321(rr), that are adulterated under 21 U.S.C. § 387b(6)(A) and misbranded under 21 U.S.C. § 387c(a)(6).

4. For the purposes of this Decree:

A. "Associated Persons" refers to Defendant's directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, affiliates, franchisees, and "doing business as" entities).

B. "Defendant's Facility" refers to 1425 SE 24th Avenue, Cape Coral, Florida 33990, and any other location(s) at which Defendant now or in the future directly or indirectly manufactures, distributes, sells, and/or offers for sale tobacco products.

C. "Defendant's website" refers to https://www.vapejunkieejuice.com and any other websites owned or

controlled by Defendant, including but not limited any websites referenced, endorsed, or adopted directly or indirectly by Defendant.

D. "ENDS products" refers to electronic nicotine delivery system products and includes devices, components, and parts that deliver aerosolized e-liquid when inhaled.

E. "E-liquids" refers to a subcategory of ENDS products that includes liquid nicotine products and nicotine containing e-liquid products (i.e., liquid nicotine or colorings, flavorings, and/or other ingredients intended to be mixed with liquid nicotine, or any combination thereof).

F. "Defendant's ENDS products" refers to ENDS products directly or indirectly manufactured by Defendant Fitzgerald.

G. "New tobacco product" refers to a tobacco product that meets the definition for such term at 21 U.S.C. § 387j(a)(1), i.e., "any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007" or "any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007."

5. Upon entry of this Decree, Defendant Fitzgerald and each and all of her Associated Persons, permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly manufacturing, distributing, selling, and/or offering for sale any new tobacco product at or from Defendant's Facilities and/or Defendant's website, unless and until:

A. The new tobacco product is listed with FDA as required under 21 U.S.C. § 387e(i) and has received marketing authorization from FDA, and such authorization remains in effect, as follows:

(1) FDA has issued a marketing granted order under section 910(c)(1)(A)(i) of the Act, 21 U.S.C. § 387j(c)(1)(A)(i), for the new tobacco product; or

(2) FDA has issued a substantial equivalence order under section 910(a)(2)(A)(i) of the Act, 21 U.S.C. § 387j(a)(2)(A)(i), for the new tobacco product; or

(3) FDA has issued an order finding the that the new tobacco product is exempt from the substantial equivalence requirements pursuant to section 905(j)(3) of the Act, 21 U.S.C. § 387e(j)(3), and Defendant Fitzgerald has satisfied the abbreviated reporting requirements in sections

905(j)(1)(A)(ii) and 905(j)(1)(B) of the Act, 21 U.S.C. §§ 387e(j)(1)(A)(ii) and 387e(j)(1)(B), for the new tobacco product;

B. FDA representatives, without prior notice and as and when FDA deems necessary, inspect Defendant's Facility and/or review Defendant's websites to determine whether the requirements of this Decree have been met and whether Defendant Fitzgerald is operating in conformity with this Decree, the Act, and its implementing regulations;

C. Defendant Fitzgerald has reimbursed FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendant Fitzgerald's compliance with Paragraph 5, at the rates set forth in Paragraph 12; and

D. FDA notifies Defendant Fitzgerald in writing that she appears to be in compliance with the requirements set forth in Paragraphs 5.A. and 5.C. of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

6. Within fourteen (14) days after entry of this Decree, Defendant Fitzgerald shall submit to FDA an affidavit that attests to the following: she is no longer affiliated with the Defendant Allen, individually, or collectively d/b/a Vape Junkie Ejuice; she has no ENDS products in her custody, control, or possession as of the date this Decree is signed; she has no access to or control over Defendant's Facility and/or Defendant's website; she is not

directly or indirectly manufacturing, distributing, selling, and/or offering for sale any new tobacco product at or from Defendant's Facilities and/or Defendant's website; and she is not introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, tobacco products, within the meaning of 21 U.S.C § 321(rr), that are adulterated under 21 U.S.C. § 387b(6)(A) and misbranded under 21 U.S.C. § 387c(a)(6).

7. Upon entry of this Decree, and after receiving FDA's written notification pursuant to Paragraph 5.D., Defendant Fitzgerald and her Associated Persons permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivery for introduction into interstate commerce tobacco products, within the meaning of 21 U.S.C. § 321(rr), that are adulterated under 21 U.S.C. § 387b(6)(A) and/or misbranded under 21 U.S.C. § 387c(a)(6); or

B. Failing to implement and continuously maintain the requirements of this Decree.

8. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report, an application, or data prepared or submitted by Defendant Fitzgerald, a review

of product labels, labeling, leaflets, websites or social media pages owned, created by, controlled by, or related to Defendant Fitzgerald (including, but not limited to, Defendant's website and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendant Fitzgerald), promotional materials, and any other media over which Defendant Fitzgerald has control, or any other information, that Defendant Fitzgerald has failed to comply with any provision of this Decree, Defendant Fitzgerald has violated the Act or its implementing regulations, or additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendant Fitzgerald in writing of the noncompliance and order Defendant Fitzgerald to take appropriate corrective action, including, but not limited to, ordering Defendant Fitzgerald to immediately take one or more of the following actions:

A. Cease manufacturing, distributing, selling, and/or offering for sale new tobacco products that lack required FDA authorization;

B. Recall, at Defendant Fitzgerald's expense, any tobacco product that is adulterated, misbranded, unlisted, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Submit additional information to FDA as requested;

D. Institute or reimplement any of the requirements set forth

in this Decree;

E. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendant Fitzgerald into compliance with this Decree, the Act, or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law. Defendant Fitzgerald shall pay all costs of recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in this paragraph, at the rates specified in Paragraph 12.

9. Upon receipt of any order issued by FDA pursuant to Paragraph 8, Defendant Fitzgerald shall immediately and fully comply with the terms of the order. Any cessation of activities under Paragraph 8.A. shall continue until Defendant Fitzgerald receives written notification from FDA that Defendant Fitzgerald appears to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendant Fitzgerald may resume such operations. After a cessation of activities under Paragraph 8.A., and while determining whether Defendant Fitzgerald appears to be in compliance with the Decree, the Act, and its implementing regulations, FDA may require Defendant Fitzgerald to reinstitute or reimplement any of the

requirements of this Decree.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendant Fitzgerald's Facility and/or review Defendant's websites and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During such inspections, FDA representatives shall be permitted to: (1) have immediate access to Defendant Fitzgerald's places of business including, but not limited to all buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material therein; (2) take photographs and make video recordings; (3) take samples of raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material; and (4) examine and copy all records relating to the receipt, preparing, processing, packing (including repacking), labeling, holding, and distribution of any and all of Defendant's products and their components and parts. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

11. Defendant Fitzgerald shall immediately provide any information

or records to FDA upon request regarding the manufacture, distribution, sale, and/or offering for sale of Defendant's ENDS products, including information or records from websites or social media pages owned, created by, controlled by, or related to Defendant Fitzgerald (including, but not limited to, Defendant's website and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendant). Defendant Fitzgerald shall submit such information or records to FDA at the address specified in Paragraph 17.

12. Defendant Fitzgerald shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendant Fitzgerald's compliance with any part of this Decree, including all transportation and associated costs for FDA investigators and experts, at the standard rates prevailing at the time the costs are incurred. Defendant Fitzgerald shall make payment to FDA within twenty (20) business days after receiving an electronic invoice for payment, which shall be sent to jsforit@gmail.com. Defendant Fitzgerald shall make payment through the Pay.gov electronic billing system, subject to all interest, fees, and penalties applicable to delinquent payments, in accordance with 31 U.S.C. § 3717 and 45 C.F.R. § 30. As of the date that this Decree is signed by the parties, these rates are: (1) $110.59 per hour or fraction thereof per representative for inspection and investigative work; (2) $132.56 per hour or

fraction thereof per representative for analytical or review work; $0.65 per mile for travel expenses by automobile; (3) the government rate or the equivalent for travel by air or other means; and (4) the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates for FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court. Defendant Fitzgerald shall notify FDA within fifteen (15) business days if the email address at which Defendant receives electronic invoices changes.

13. In the event that Defendant Fitzgerald becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendant shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested) to such Associated Person(s). Within five (5) business days after each time Defendant Fitzgerald becomes associated with any additional Associated Person, Defendant Fitzgerald shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

14. If Defendant Fitzgerald fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendant Fitzgerald shall pay to the United States of America: (1) five thousand dollars ($5,000) in liquidated damages for each day such violation continues; (2) an additional sum of four thousand dollars ($4,000) in liquidated damages per day per violation, for each violation of this Decree, the Act, or its implementing regulations; and (3) an additional sum in liquidated damages equal to twice the retail value of any product distributed in violation of this Decree, the Act, or its implementing regulations. Defendant Fitzgerald understands and agrees that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the Court to impose, additional civil or criminal penalties to be paid by Defendant Fitzgerald, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

15. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendant Fitzgerald shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

16. Defendant Fitzgerald shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

17. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall (1) be prominently marked "Decree Correspondence," (2) reference this civil action by case name and civil action number, and (3) be submitted electronically to the Center for Tobacco Products Office of Compliance and Enforcement, at CTPCompliance@fda.hhs.gov. If electronic submission is not possible, communications shall be addressed to the attention of Division Director, Division of Enforcement and Manufacturing, Office of Compliance and Enforcement, FDA Center for Tobacco Products, c/o Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

18. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

19. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this 4th day of March, 2024.

SHERI POLSTER CHAPPELL
UNITED STATES DISTRICT JUDGE