UNITED STATES OF AMERICA
BEFORE THE DEPARTMENTAL APPEALS BOARD
CIVIL REMEDIES DIVISION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Case of: Center for Tobacco Products, Complainant, v. Great American Vapes LLC d/b/a Great American Vapes, Respondent.	**ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY** FDA Docket No. FDA-2023-U-0483 CRD Docket No. T-23-1065

INTRODUCTION

1. The Center for Tobacco Products (CTP), Food and Drug Administration (FDA), United States Department of Health and Human Services, seeks a civil money penalty (CMP) in the amount of $19,192 from Great American Vapes LLC, d/b/a Great American Vapes (Respondent), a manufacturer and retailer of new tobacco products that lack the premarketing authorization required under the Federal Food, Drug, and Cosmetic Act (Act).

LEGAL AUTHORITY

2. Any person who violates a requirement of the Act which relates to tobacco products shall be liable for a civil money penalty up to $19,192 for each such violation, not to exceed $1,279,448 for all violations adjudicated in a single

proceeding.[1] 21 U.S.C. § 333(f)(9)(A); 21 C.F.R. § 17.2, referencing 45 C.F.R. § 102.3 (setting forth, among other things, the current maximum CMP amount for violations of requirements of the Act which relate to tobacco products, adjusted for inflation).

3. The term "person" is defined to include individuals, partnerships, corporations, and associations. 21 U.S.C. § 321(e).

4. It is a violation of the Act to cause a tobacco product to become adulterated or misbranded while it is held for sale after shipment of one or more of its components in interstate commerce. 21 U.S.C. § 331(k).

5. "Interstate commerce" includes "commerce between any State or Territory and any place outside thereof." 21 U.S.C. § 321(b).

6. A "tobacco product" means "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." 21 U.S.C. § 321(rr).

7. FDA's authority over tobacco products is found in Chapter IX of the Act. *See* 21 U.S.C. § 387a(b) (Chapter IX of the Act applies to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and [ ] any other tobacco products that [FDA] by regulation deems to be subject to this chapter").

[1] The Tobacco Control Act provides a penalty schedule applicable in civil money penalty cases brought against tobacco product retailers for violations of the federal minimum age for sale of tobacco products and violations of FDA's tobacco product regulations restricting the sale, distribution, and use of cigarettes, smokeless tobacco, and covered tobacco products in 21 C.F.R. Part 1140. That penalty schedule does not apply in this matter, which is against a tobacco product manufacturer and alleges violations relating to failure to have required FDA premarket authorization for new tobacco products.

8. As of August 8, 2016, FDA deemed additional products meeting the definition of a tobacco product, except accessories to these newly deemed products, to be subject to regulation under the Act. These products include, but are not limited to, electronic nicotine delivery systems (including e-cigarettes), e-liquids, cigars, and pipe tobacco. *See* 81 Fed. Reg. 28,974 (May 10, 2016), available at https://federalregister.gov/a/2016-10685.

9. 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."

10. All new tobacco products must have FDA authorization prior to their marketing. *See* 21 U.S.C. § 387j(a)(2)(A).

11. A new tobacco product may receive FDA marketing authorization through any one of three pathways:

    a. 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;

    b. 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 (SE 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 to a tobacco product marketed after that date, but which FDA previously determined to be substantially equivalent; or

c. 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).

12. 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). 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).

13. 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).

CURRENT ALLEGATIONS

14. Respondent manufactures tobacco products and holds them for sale at its establishment that does business under the name Great American Vapes and is located at 934 East 70th Street, Shreveport, LA 71106.

15. Respondent receives at least one component that it uses to manufacture its tobacco products from outside of Louisiana.

16. On October 7, 2021, although there is no statutory requirement for FDA to do so, CTP issued a Warning Letter to Respondent, stating that, among other things,

the new tobacco products that Respondent manufactures, sells, and/or distributes were adulterated and misbranded because they lacked the required FDA marketing authorization order.

17. On December 2, 2022, an FDA-commissioned inspector conducted an inspection of Great American Vapes. The inspector observed Respondent's e-liquid products, including Great American Vapes Krispie Treats Xtra Flav 3mg 50ml e-liquid product, available for sale at Respondent's establishment.

18. Respondent's e-liquid products are "new tobacco product" because they were not commercially marketed in the United States as of February 15, 2007.

19. Respondent's e-liquid products do not have an SE order or found-exempt order in effect. Accordingly, they are required by 21 U.S.C. § 387j(a) to have premarket review.

20. Respondent submitted a PMTA to FDA for certain of its e-liquid products, and on September 3, 2021, FDA issued a marketing denial order (MDO) for these e-liquid products.

21. Respondent's e-liquid products do not have an MGO in effect under 21 U.S.C. § 387j(c)(1)(A)(i) and they are, therefore, adulterated under 21 U.S.C. § 387b(6)(A).

22. Neither an SE report nor an abbreviated report has been submitted for Respondent's e-liquid products, and they are, therefore, misbranded under 21 U.S.C. § 387c(a)(6).

23. Respondent's failure to obtain the required premarket authorization for its new tobacco products causes them to become adulterated and misbranded while they

are held for sale after shipment of one or more of their components in interstate commerce, in violation of 21 U.S.C. § 331(k).

RESPONDING TO COMPLAINT

24. Respondent must respond to this Complaint. The cover letter provides information on options for responding. Respondent has the right to request a hearing by filing an Answer within 30 days after service of the Complaint. 21 C.F.R. § 17.9. The Answer will be deemed to be a request for a hearing unless the Answer states otherwise. Failure to file an Answer within 30 days after service of the Complaint may result in a default order imposing the proposed civil money penalty. 21 C.F.R. § 17.11. The Answer must be filed with the Departmental Appeals Board, Civil Remedies Division. Answers should be filed electronically at https://dab.efile.hhs.gov or, to request a waiver from filing an Answer electronically with DAB E-File, Respondent should call the Civil Remedies Division of the Departmental Appeals Board at 844-880-5720. For additional instructions on how to file an Answer, *see* the Cover Letter that accompanies this Complaint.

25. Respondent has the right, but is not required to, retain counsel for representation.

REQUEST FOR RELIEF

26. CTP respectfully requests an order assessing a civil money penalty against Respondent in the amount of $19,192.

DATED: February 15, 2023

Respectfully submitted,

/s/

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