



May 1, 2018

VIA UPS and Electronic Mail

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WARNING LETTER

Dear Michael Eshragh:

This is to advise you that the Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) and the U.S. Federal Trade Commission recently reviewed the website <http://www.omniaeliquid.com>, from which you take orders for Twirly Pop e-liquid products. FDA has determined that the e-liquid products listed there are manufactured and offered for sale or distribution to customers in the United States. Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), these products are tobacco products because they are made or derived from tobacco and intended for human consumption. Certain tobacco products, including e-liquids, are subject to FDA jurisdiction under section 901(b) of the FD&C Act (21 U.S.C. § 387a(b)). In addition, the FTC has reviewed your marketing for Twirly Pop e-liquid under Section 5 of the FTC Act, 15 U.S.C. § 45(a).

FD&C Act Violations

1. False or Misleading Violation

FDA has determined that your Twirly Pop e-liquid is misbranded under section 903(a)(1) of the FD&C Act (21 U.S.C. § 387c(a)(1)) and/or section 903(a)(7)(A) of the FD&C Act (21 U.S.C. § 387c(a)(7)(A)) because its labeling and/or advertising is false or misleading.

FDA's investigation of the website <http://www.omniaeliquid.com> revealed that it sells or distributes Twirly Pop e-liquid with labeling and/or advertising that causes it to imitate food products, particularly ones that are marketed toward, and/or appealing to, children (see Exhibit A). Specifically, the labeling and/or advertising of the product looks very similar to lollipops that are marketed toward, and/or appealing to, children, such as Unicorn Pops, Whirly Pop, and Twirl Pops lollipops (see Exhibit B). For example, the labeling and/or advertising for Twirly Pop e-liquid includes a label with a rainbow swirled background that resembles a swirled, cylindrical lollipop, such as the Unicorn Pop, and is evocative of other lollipops, such as Whirly Pop and Twirl Pop. Twirly Pop e-liquid is also co-packaged with a Unicorn Pop, a rainbow and unicorn-themed lollipop that the product closely resembles. In addition, the labeling and/or advertising prominently displays the name "Twirly Pop" and depicts the "o" in "Twirly Pop" as an illustrated

lollipop that is substantially similar to the labeling on both Whirly Pop lollipops and Twirl Pop lollipops. Further, the website <http://www.omniaeliquid.com> and the Instagram page for Twirly Pop e-liquid contain statements and representations such as: “YOUR FAVORITE RAINBOW FLAVORED LOLLIPOP!”; “Who doesn’t love this candy!!??”; “Trick or Treat!! Wouldn’t you love this in your bag tonight!?!?”; and “YOU LIKE THIS [referring to a Whirly Pop lollipop]?? You will love Twirly Pop.” Further, Twirly Pop e-liquid has a strong scent like Unicorn Pops lollipops. This labeling and/or advertising causes the product to imitate lollipops, particularly ones that are marketed toward, and/or appealing to, children and is therefore misleading.



Exhibit A



Exhibit B

Children are at particular risk for ingesting e-liquid products with labeling and/or advertising that causes the product to imitate a food or beverage, particularly a food or beverage that is typically marketed toward, and/or appealing to, children. Moreover, children are at particular risk because exposure to the nicotine in the e-liquid product, even in relatively small amounts, could result in acute toxicity. Child poisonings due to the ingestion of liquid nicotine have recently increased substantially. Severe harms can occur in small children from ingestion of liquid nicotine, including death from cardiac arrest, as well as seizure, coma, and respiratory arrest.

Given that the labeling and/or advertising on Twirly Pop e-liquid describes its nicotine content as 6mg/mL, with a total volume of 60mL, an accidental ingestion of approximately half a teaspoon would reach the lower end of the fatal dose range for an average two-year-old. Additionally, an accidental ingestion of approximately 2% of a teaspoon would reach the lower end of the non-fatal acute toxicity range for an average two-year-old.

The FD&C Act provides, in part, that a tobacco product shall be deemed to be misbranded (1) if its labeling is false or misleading in any particular (section 903(a)(1)), or (2) if the tobacco product is distributed or offered for sale in any State and its advertising is false or misleading in any particular (section 903(a)(7)(A)). The labeling and/or advertising for Twirly Pop e-liquid is misleading because it causes the product to imitate lollipops, particularly ones that are marketed toward, and/or appealing to, children. Therefore, the product is misbranded under section 903(a)(1) and/or 903(a)(7)(A) of the FD&C Act.

2. Sales to Minors Violation

FDA also has determined that your Twirly Pop e-liquid is misbranded under section 903(a)(7)(B) of the FD&C Act (21 U.S.C. § 387c(a)(7)(B)) because you sold this product to a person younger than 18 years of age.

FDA's investigation of the website <http://www.omniaeliquid.com> revealed that you sold an e-liquid product to a minor. Specifically, during our investigation of <http://www.omniaeliquid.com>, a person younger than 18 years of age purchased Twirly Pop e-liquid from your website. No retailer may sell covered tobacco products, including e-liquid, cigar, pipe tobacco, waterpipe tobacco, and dissolvable tobacco products, as well as electronic nicotine delivery system (ENDS) products that contain any tobacco derivative, to a person younger than 18 years of age under 21 C.F.R. § 1140.14(b). Under 21 C.F.R. § 1140.3, a "covered tobacco product" is defined as any tobacco product deemed to be subject to chapter IX of the FD&C Act by 21 C.F.R. § 1100.2, excluding components or parts not made or derived from tobacco. Before 21 C.F.R. § 1100.2 became effective, only cigarettes, smokeless tobacco, roll-your-own tobacco, and cigarette tobacco were subject to chapter IX of the FD&C Act. 21 C.F.R. § 1100.2 deems all other tobacco products, except accessories of such tobacco products, subject to chapter IX and its implementing regulations. The product cited in this violation is a "covered tobacco product." Under section 903(a)(7)(B) of the FD&C Act (21 U.S.C. § 387c(a)(7)(B)), tobacco products are misbranded if sold or distributed in violation of regulations prescribed under section 906(d) of the FD&C Act, including those within 21 C.F.R. Part 1140. Because this product is sold or distributed to persons younger than 18 years of age in violation of 21 C.F.R. § 1140.14(b), this product is misbranded under section 903(a)(7)(B) of the FD&C Act (21 U.S.C. § 387c(a)(7)(B)).

3. Marketing Tobacco Products in Combination with Any Other FDA Regulated Product Violation

Additionally, FDA has determined that your Twirly Pop e-liquid violates section 201(rr)(4) of the FD&C Act (21 U.S.C. § 321(rr)(4)) because it is marketed in combination with food.

FDA's investigation of the website <http://www.omniaeliquid.com> revealed that it markets and co-packages for sale Twirly Pop e-liquid in combination with a food product. Under section 201(rr)(4) of the FD&C Act (21 U.S.C. § 321(rr)(4)), a tobacco product shall not be marketed in combination with any other article or product regulated under the FD&C Act, including a drug, biologic, food, cosmetic, medical device, or dietary supplement. You marketed and co-packaged for sale Twirly Pop e-liquid in combination with Unicorn Pop lollipops, a food that is regulated under the FD&C Act. Accordingly, you violated the prohibition in section 201(rr)(4) of the FD&C Act.

The FD&C Act violations discussed in this letter do not necessarily constitute an exhaustive list. You should immediately correct the violations that are referenced above, as well as violations that are the same as or similar to the ones stated above, and take any necessary actions to bring your tobacco products into compliance with the FD&C Act.

It is your responsibility to ensure that your tobacco products and all related labeling and/or advertising on this website, on any other websites (including e-commerce, social networking, or search engine websites), and in any other media in which you advertise, and in any retail establishments comply with each applicable provision of the FD&C Act and FDA's implementing regulations. Failure to ensure full compliance with the FD&C Act may result in FDA initiating further action without notice, including, but not limited to, civil money penalties, no-tobacco-sale orders, criminal prosecution, seizure, and/or injunction. Please note that any adulterated and misbranded tobacco products offered for import into the United States are subject to detention and refusal of admission.

Unfair or Deceptive Marketing

In addition, the Federal Trade Commission has reviewed the online marketing of Twirly Pop e-liquid. Section 5 of the FTC Act prohibits unfair or deceptive acts or practices in or affecting commerce. This prohibition includes practices that present unwarranted health or safety risks. Commission Policy Statement on Unfairness, 104 F.T.C. 1070, 1071 (1984) (*appended to Int'l Harvester Co.*, 104 F.T.C. 949 (1984)), *available at* <https://www.ftc.gov/public-statements/1980/12/ftc-policy-statement-unfairness>. Preventing practices that present unwarranted health and safety risks, particularly to children, is one of the Commission's highest priorities. FTC Strategic Plan for 2018-2022, at 6; *Philip Morris, Inc.*, 82 F.T.C. 16 (1973).

As noted above, Twirly Pop e-liquid is marketed in packaging that resembles rainbow-flavored lollipop candies, and the e-liquid is co-packaged with an actual Unicorn Pop lollipop. A rainbow sticker is also included in the packaging. Twirly Pop e-liquid has a scent almost identical to the Unicorn Pop lollipop included in the packaging and the odor is detectible without opening the packaging. Given the significant number of serious child poisonings due to the ingestion of liquid nicotine, packaging Twirly Pop e-liquid in a manner that is likely to be particularly appealing to young children could present an unwarranted risk to health and safety.

The FTC strongly urges you to review your marketing, including packaging, for Twirly Pop e-liquid and similarly marketed products and to take swift and appropriate steps to protect consumers, especially young children.

Conclusion and Requested Actions

With regard to the FD&C Act violations described in this letter, please submit a written response to this letter within 15 working days from the date of receipt describing your corrective actions, including the dates on which you discontinued the violative labeling, advertising, sale, and/or distribution of these tobacco products and your plan for maintaining compliance with the FD&C Act. If you do not believe that your products are in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. You can find the FD&C Act through links on FDA's homepage at <http://www.fda.gov>.

Please note your reference number, RW1800862, in your response and direct your response to the following address:

DPAL-WL Response, 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

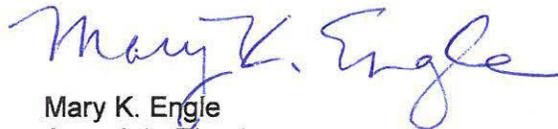
If you have any questions, please contact Ele Ibarra-Pratt at (301) 796-9235 or via email at CTPCompliance@fda.hhs.gov.

With regard to the FTC-related issues described in this letter, please notify Rosemary Rosso of the FTC via electronic mail at rosso@ftc.gov within 15 days of receipt of this letter of the specific actions you have taken to address the FTC's concerns.

Sincerely,



Ann Simoneau, J.D.
Director
Office of Compliance and Enforcement
Center for Tobacco Products



Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission

VIA Electronic Mail

cc:

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