



May 1, 2018

**VIA UPS and Electronic Mail**

Ali Esmaili and Jameson Rodgers  
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**WARNING LETTER**

Dear Ali Esmaili and Jameson Rodgers:

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 (FTC) recently reviewed the website <http://www.madhatterjuice.com> from which you take orders for the One Mad Hit Juice Box e-liquid product. 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, 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 One Mad Hit Juice Box e-liquid under Section 5 of the FTC Act, 15 U.S.C. § 45(a).

**FD&C Act Misbranding Violation**

FDA has determined that your One Mad Hit Juice Box 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.madhatterjuice.com> revealed that it sells or distributes One Mad Hit Juice Box e-liquid with labeling and/or advertising that causes it to imitate a food or beverage, particularly one that is marketed toward, and/or appealing to, children (see Exhibit A). Specifically, the labeling and/or advertising of the product looks very similar to the labeling and/or advertising for juice boxes that are commonly marketed toward children (see Exhibit B). For example, the labeling and/or advertising for One Mad Hit Juice Box e-liquid includes statements and representations, such as "Juice Box," "juicy apple juice," "A Juicebox a Day Keeps the Doctor Away," "Serving Size 1 bottle," and "real red apples," as well as a label on the back that is substantially similar to a food Nutrition Facts label. In addition, the labeling and/or advertising of One Mad Hit Juice Box e-liquid includes: the appearance of folded over and sealed top corners of the product's packaging that is substantially similar to the aseptic, shelf-stable packages in which juice boxes are sold; an image of a straw wrapped in

clear plastic affixed to the side of the packaging; images of apples and apple trees; and a color scheme that is substantially similar to the juice boxes in Exhibit B. Further, One Mad Hit Juice Box e-liquid has a strong scent like apple juice. This labeling and/or advertising causes the product to imitate a food or beverage, particularly one that is 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 One Mad Hit Juice Box e-liquid describes its nicotine content as 3mg/mL, with a total volume of 180mL, an accidental ingestion of slightly less than a teaspoon would reach the lower end of the fatal dose range for an average two-year-old. Additionally, an accidental ingestion of approximately 3% 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 One Mad Hit Juice Box e-liquid is misleading because it causes the product to imitate a food or beverage, particularly one that is 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.

The FD&C Act violation discussed in this letter does not necessarily constitute an exhaustive list. You should immediately correct the violation that is referenced above, as well as violations that are the same as or similar to the one 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), 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, 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 One Mad Hit Juice Box 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, One Mad Hit Juice Box e-liquid products are marketed in packaging that very closely resembles apple juice boxes targeted to and primarily consumed by young children. The e-liquid product has a scent identical to apple juice and the odor is detectable without opening the packaging. Given the significant number of serious child poisonings due to the ingestion of liquid nicotine, packaging One Mad Hit e-liquid products 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 One Mad Hit e-liquid products 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 violation 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, RW1800836, 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 [CTPCCompliance@fda.hhs.gov](mailto:CTPCCompliance@fda.hhs.gov).

With regard to the FTC-related issues described above, please notify Rosemary Rosso of the FTC via electronic mail at [rosso@ftc.gov](mailto: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 UPS and Electronic Mail**

cc:

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