

EZ Fumes 4/4/19



Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

VIA UPS and Electronic Mail

APRIL 4, 2019

Mike Makhani
EZ Fumes
2900 Highway 121 # 165
Bedford, Texas 76021
ezfumes@gmail.com

WARNING LETTER

Dear Mike Makhani:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) recently reviewed the website <https://www.ezfumes.com> and determined that the e-liquid products listed there are 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)).

FDA has determined that your Double Cup Liquids Spritech Lemon Lime E-Juice Syrup and Double Cup Liquids Pineapple Phantom Flavor E-Juice Syrup e-liquid products are 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 their labeling and/or advertising are false or misleading.

Tobacco Products With False or Misleading Labeling and/or Advertising Are Misbranded

FDA's investigation of the website <https://www.ezfumes.com> revealed it advertises and sells or distributes Double Cup Liquids Spritech Lemon Lime E-Juice Syrup and Double Cup Liquids Pineapple Phantom Flavor E-Juice Syrup e-liquid products with labeling and/or advertising that cause the products to appear to be ingestible, when they are

not (see Exhibits A and C, respectively). Adults and children are at risk from ingestion of liquid nicotine when nicotine-containing e-liquid products misleadingly appear to be ingestible because ingestion of the nicotine in the e-liquid products, even in relatively small amounts, could result in severe harms such as death from cardiac arrest, as well as seizure, coma, and respiratory arrest.

Double Cup Liquids Spritech Lemon Lime E-Juice Syrup

The labeling and/or advertising for Double Cup Liquids Spritech Lemon Lime E-Juice Syrup e-liquid include statements, representations, and graphical elements that cause the product to appear ingestible by imitating the cough syrup Actavis Prometh with Codeine (see Exhibit B). For example, the bottle's labeling features: the term "actright," set against a triangular orange banner at the top left of the label, similar to the placement of "Actavis" on the drug product; a list of ingredients, the color, font, and formatting of which imitates the drug fact label on the Actavis product; the word "vape" enveloped by a "C" at the top left of the label, similar to the image of a "v" enveloped by a "C" on the Actavis product; a teardrop shape appearing at the bottom of the label in the same place as on the Actavis product; and the word "Syrup," which also appears on the Actavis cough syrup product. Actavis Prometh with Codeine Cough Syrup is intended to be taken orally at a recommended dosage of 5mL – 10mL. Thus, by imitating the Actavis product, the e-liquid product suggests it is meant to be ingested like cough syrup.



Exhibit A



Exhibit B

The labeling and/or advertising of Double Cup Liquids Spritech Lemon Lime E-Juice Syrup e-liquid also contain statements, representations, and graphical elements that make the product appear to be ingestible as a food. For example, the outer packaging is shaped to give it the appearance of a Styrofoam beverage cup, contains the terms "Double Cup" and "Who Got The Juice," appears to contain ice cubes and drip with syrupy beverage from the mouth of the cup, and has an image of what appears to be a Styrofoam beverage cup. The bottle label also sets the terms "Spritech," "Lemon Lime," and "Syrup" against a background that appears to depict purple syrup dripping over the label. In addition, this e-liquid has a strong, sweet scent that is detectible without opening the bottle.

Double Cup Liquids Pineapple Phantom E-Juice Syrup

The labeling and/or advertising of Double Cup Liquids Pineapple Phantom E-Juice Syrup e-liquid include statements, representations, and graphical elements that cause the product to appear ingestible by imitating the cough syrup Hi-Tech Promethazine Hydrochloride and Codeine Phosphate Syrup (see Exhibit D). For example, the bottle label features: a rectangular banner containing the terms “Hi-Taste,” which is similar in appearance to the rectangular banner on the Hi-Tech product containing the term “Hi-Tech;” a watermark of the term “vape” enveloped by “C,” similar to the watermark on the Hi-Tech product of a “v” enveloped by “C;” a list of ingredients, the color, font, and formatting of which imitates the drug fact label on the Hi-Tech product; and the word “Syrup,” which also appears on the Hi-Tech cough syrup product. Hi-Tech Promethazine Hydrochloride and Codeine Phosphate Syrup is intended to be taken orally at a recommended dosage of 5mL – 10mL. Thus, by imitating the Hi-Tech product, the e-liquid product suggests it is meant to be ingested like cough syrup.



Exhibit C



Exhibit D

The labeling and/or advertising of Double Cup Liquids Pineapple Phantom E-Juice Syrup e-liquid also contain statements, representations, and graphical elements that make the product appear to be ingestible as a food. For example, the outer packaging is shaped like a cup to give it the appearance of a Styrofoam beverage cup, contains the terms “Double Cup” and “Who Got The Juice,” appears to contain ice cubes and drip with syrupy beverage from the mouth of the cup, and has an image of what appears to be a Styrofoam beverage cup. The bottle label also sets the terms “Pineapple Phantom” and “Syrup” against a background that appears to depict yellow syrup dripping over the label. In addition, this e-liquid has a strong, sweet scent that is detectible without opening the bottle.

The overall presentations of the e-liquid products, including of their respective names and the accompanying statements, representations, and graphical elements on their labeling and/or advertising, make it appear that the products are ingestible products, such as cough syrup products or beverages, and could reasonably result in a child or adult ingesting the products. Because the labeling and/or advertising cause the products to appear to be ingestible products, when they are not, the labeling and/or advertising are misleading.

Adults and children are at risk of poisoning by nicotine-containing e-liquid products that appear to be ingestible, when they are not. An adult might mistakenly ingest these products, of which a small amount could result in acute toxicity. Likewise, nicotine exposures of these sorts are extremely problematic and could be fatal for children. 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 of Double Cup Liquids Spritech Lemon Lime E-Juice Syrup and Double Cup Liquids Pineapple Phantom E-Juice Syrup e-liquids describe their nicotine content as being as high as 6mg/mL, with a total volume of 60mL, an accidental ingestion of slightly less than 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 average adult dosage of codeine cough syrup is 5mL – 10mL. At the high cough syrup dosage, 10mL, e-liquid with a nicotine content of 6mg/mL thought to be cough syrup would expose an adult to 60mg of nicotine, which could cause moderate or fatal nicotine toxicity, depending upon inter-individual differences in adult toxicity responses.

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 Double Cup Liquids Spritech Lemon Lime E-Juice Syrup and Double Cup Liquids Pineapple Phantom E-Juice Syrup e-liquids cause the products to appear to be ingestible products, when they are not, and are therefore misleading. Therefore, the products are misbranded under sections 903(a)(1) and/or 903(a)(7)(A) of the FD&C Act.

Conclusion and Requested Actions

The 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.

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> (<http://www.fda.gov>).

Please note your reference number, RW1901057, 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 about the content of this letter, please contact Ele Ibarra-Pratt at (301) 796-9235 or via email at CTPCCompliance@fda.hhs.gov (<mailto:CTPCCompliance@fda.hhs.gov>).

Sincerely,
/S/
Ann Simoneau, J.D.
Director

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Center for Tobacco Products

VIA UPS and Electronic Mail

cc:

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