
This letter is issued by the U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) regarding the U.S. Food and Drug Administration (FDA) and the Federal www.maryjanesbakeryco.com and www.miamirave.com

_____ in February, March, April and June 2024, respectively, and have determined that you take orders there for various products that you represent as containing Delta-8 tetrahydrocannabinol (THC). FDA has determined that your Stoney Sour Gummy Bears: 1,000mg Delta-8 THC, Stoney Ranchers Hard Candy: 1,000mg Delta-8 THC, Dank Ropes: 1,000mg Delta-8 THC, Stoney Patch Sour Watermelon Slices: 1,000 mg Delta-8 THC, Slizzles: 1,000mg Delta-8 THC, Flaming Hot Weedos: 1,000mg Delta-8 THC, and Trips Ahoy Chocolate Chip Cookies: 1,000mg Delta-8 THC products are adulterated under section 402(a)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(2)(C)(i), because they bear or contain an unsafe food additive. It is a prohibited act to introduce adulterated food into interstate commerce under section 301(a) of the Act, 21 U.S.C. 331(a).

_____ and FDA is not enforcing this law, since you are not in the U.S. and FDA regulations through links

_____. You can find specific information about how FDA

Mary Jane's Bakery Co.

substance is generally recognized as safe (GRAS) among qualified experts under the conditions of its intended use, or unless the substance meets a listed exception.²

Food additives require premarket approval based on data demonstrating safety. Any food additive that has not been approved for its intended use in food is deemed to be unsafe under section 409(a) of the Act (21 U.S.C. 348(a)) and causes the food to be adulterated under section 402(a)(2)(C)(i) of the Act, 21 U.S.C. 342(a)(2)(C)(i). Introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. 331(a).

There is no food additive regulation that authorizes the use of Delta-8 THC. We are not aware of any information to indicate that Delta-8 THC is the subject of a prior sanction (see 21 CFR Part 181). Furthermore, we are not aware of any basis to conclude that Delta-8 THC is GRAS for use in conventional foods. FDA's regulations in 21 CFR 170.30(a)-(c) describe the criteria for eligibility for classification of a food ingredient as GRAS. The use of a food substance may be GRAS based on either scientific data or a history of use in food.

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contain an unsafe food additive. Introduction of an adulterated food into interstate commerce is

As noted above, your various Delta-8 THC products have an appearance and form similar to conventional snack foods often consumed by children. Your Trips Ahoy chocolate chip cookies are sold in packaging that closely resembles that for Nabisco Chips Ahoy cookies, including the use of a blue background, the depiction of a chocolate chip cookie with a bite taken out on the left side displayed underneath the word "ORIGINAL" in all caps in a white font that mimics handwriting, and the use of a similar color scheme and font for the "Trips Ahoy!" logo as that used for Chips Ahoy! logo. Your Slizzles product comes in packaging closely resembling that for Sour Skittles, including the use of a lime green background, the inclusion of a rainbow ribbon graphical element, the depiction of colored oblate spheroid candies printed with a white small letter "s," and the use of a similar font for the white "Slizzles" logo as that used for Skittles, including the use of a piece of candy to dot the letter "i." Similarly, the packaging for your Stoney Patch Sour Watermelon Slices, Stoney Ranchers Hard Candy, Dank Ropes, and Flaming Hot Weedos contain color schemes and graphical elements that resemble those for Sour Patch Kids Watermelon Candy, Jolly Rancher hard candy, Nerds Rope, and Flamin' Hot Cheetos, respectively. Your Stoney Patch Candy (Blue, Orange, and Purple) and Dank Ropes (Blue, Orange, and Purple) also resemble the packaging for Sour Patch Kids Candy (Blue, Orange, and Purple) and Nerds Rope (Blue, Orange, and Purple), respectively.

cdelorme@ftc.gov within 15 working days of receipt of this letter of the specific actions you have taken to address the FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Ms. DeLorme at (202) 326-2095.

Sincerely,

Ann M. Oxenham
Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Sincerely,

A handwritten signature in red ink that reads "Serena Viswanathan". The signature is written over a background of a colorful, pixelated pattern.

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission

cc:

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