



WARNING LETTER

VIA E-MAIL

Shamrockshrooms.com  
[shamrockshrooms@gmail.com](mailto:shamrockshrooms@gmail.com)  
[checkla2020@gmail.com](mailto:checkla2020@gmail.com)

RE: 675517

To Whom It May Concern:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address <https://shamrockshrooms.com> October 2023, February and March 2024, and in 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 Errlli Delta-8 THC Shark Gummies, Errlli Delta-8 THC Sour Brite Crawlers, and Errlli Delta-8 Sour Glowworms, 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).

As explained further below, introducing or delivering these products for introduction into interstate commerce violates the Act, a serious health risk to consumers. (5h] Â-

FDA is particularly concerned that your products are in forms (e.g., candy) that are appealing to children, that mimic wellknown snack food brands by using similar brand names, logos, or pictures on packaging, and that consumers may confuse with traditional products. Therefore, with these products there is a risk of unintended consumption of the Delta-8 THC ingredient by consumers. In June 2022, FDA warned consumers about the accidental ingestion by children of food products containing THC. From January 1, 2021, through December 31, 2023, FDA received over 300 adverse event reports describing children and adults who consumed Delta-8 THC products. Nearly half of the reports involved hospitalization or emergency department visits, and approximately two-thirds described adverse events after ingestion of Delta-8 THC-containing food products such as candy or brownies. Your Errlli Delta-8 THC Shark Gummies, Errlli Delta-8 THC Sour Brite Crawlers, and Errlli Delta-8 Sour Glowworms are all in forms that may be attractive to children.

Therefore, we are requiring you to revise the labeling of your products to include the following information: (i) a warning statement that reads: "This product contains Delta-8 THC, a psychoactive substance that can cause intoxication and impairment of judgment. Do not drive or operate heavy machinery while using this product." (ii) a statement that reads: "This product is not intended for use by children, pregnant women, or individuals with a history of heart disease, high blood pressure, or other medical conditions." (iii) a statement that reads: "This product is not intended for use by individuals who are taking medications that may interact with Delta-8 THC, such as blood thinners, antidepressants, and sedatives." (iv) a statement that reads: "This product is not intended for use by individuals who are taking medications that may interact with Delta-8 THC, such as blood thinners, antidepressants, and sedatives." (v) a statement that reads: "This product is not intended for use by individuals who are taking medications that may interact with Delta-8 THC, such as blood thinners, antidepressants, and sedatives." (vi) a statement that reads: "This product is not intended for use by individuals who are taking medications that may interact with Delta-8 THC, such as blood thinners, antidepressants, and sedatives." (vii) a statement that reads: "This product is not intended for use by individuals who are taking medications that may interact with Delta-8 THC, such as blood thinners, antidepressants, and sedatives." (viii) a statement that reads: "This product is not intended for use by individuals who are taking medications that may interact with Delta-8 THC, such as blood thinners, antidepressants, and sedatives." (ix) a statement that reads: "This product is not intended for use by individuals who are taking medications that may interact with Delta-8 THC, such as blood thinners, antidepressants, and sedatives." (x) a statement that reads: "This product is not intended for use by individuals who are taking medications that may interact with Delta-8 THC, such as blood thinners, antidepressants, and sedatives."

We know of no basis for general recognition of safety for Delta-8 THC based either on scientific procedures or common use in food prior to January 1, 1958. Based on our review of published scientific literature, existing data and information do not provide an adequate basis to conclude that the use of Delta-8 THC in food meets the criteria for GRAS status. Some of the available data raise serious concerns about potential harm from Delta-8 THC. Our review of published scientific literature identified potential for adverse effects on the central nervous and cardiopulmonary systems. In addition, studies in animals have suggested that gestational exposure to Delta-8 THC can interfere with neurodevelopment. Therefore, based on our review the use of Delta



number of adverse events reported in connection with ingestion of edible products containing THC, advertising and packaging your Delta-8 THC products in a manner that is likely to be particularly appealing to young children could present an unwarranted risk to health and safety.

You must immediately cease marketing edible Delta-8 THC products that imitate conventional foods using advertising or packaging that is likely to be appealing to young children. The FTC also strongly urges you to review all of your marketing and product packaging for similar edible THC products, and to take swift and appropriate steps to protect consumers, especially young children.

With regard to the FTC-related issues described in this letter, please notify Christine DeLorme, attorney with the FTC's Division of Advertising Practices, via electronic mail at [cdelorme@ftc.gov](mailto: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) 326-2265.

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 horizontal line of colorful, multi-colored noise or a corrupted image.

Serena Viswanathan  
Associate Director  
Division of Advertising Practices  
Federal Trade Commission

Cc:  
Domains by Proxy, Inc.  
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