



Life Leaf Medical CBD Center
Attn: Spencer Willis
11871 Plaza Dr. Unit 4
Murrells Inlet, SC 29576-7450
wordpress@lifeleafmedical.com
lifeleaf@sccoast.net

RE: 674917

Dear Mr. Willis:

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 www.lifeleafmedical.com in November 2023, in January, March, and April 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

See <https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc>. This letter is to inform you that your firm markets Delta-8 THC-containing products that may pose a serious health risk to consumers.

FDA is particularly concerned that your products are in forms (e.g., candy, cookies and snacks) that are appealing to children, that mimic well-known snack food brands by using similar brand names, logos, or pictures on packaging, and that consumers may confuse with traditional foods. 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.¹ 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

no basis to conclude that any intended use in food of any cannabinoid satisfies the criteria for eligibility for GRAS status.

Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to address any violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective actions within fifteen working days, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration.

Your response should be sent to CFSANResponse@fda.hhs.gov. Please include “CMS 674917” in the subject line of your email.

In addition, the FTC has reviewed the online marketing of the Delta-8 THC products referenced above. 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)); *see also Philip Morris, Inc.*, 82 F.T.C. 16 (1973) (alleging that distribution of sample razor blades without protective packaging in home-delivered newspapers was a health and safety hazard, particularly to young children, that violated Section 5). Preventing practices that present unwarranted health and safety risks, particularly to children, is one of the Commission’s highest priorities. FTC Strategic Plan for Fiscal Years 2022-2026 at 5.

As noted above, your Delta-8 THC products have an appearance and form similar to conventional snack foods often consumed by children. Your Delta 8 THC Nerds Rope product strongly resembles Nerds Rope candy, with both products comprising multi-colored crunchy candies attached to a gummy rope. Further, the packaging for your product features a brightly-colored background, the blue and white Nerds logo, and what appears to be the Nerds mascot (a cartoon anthropomorphic Nerds candy with two eyes, a prominent round nose, and two legs. Your Delta-8 THC Cereal Treats are sold in packaging that not only depicts multi-colored crispy rice cereal on the front, but also is clear plastic on the back side, clearly revealing the crispy rice cereal treats inside. Your Double Stuff Stoneo cookies are sold in packaging that mimics that of Nabisco Double Stuf Oreos. The packaging for both features a large single chocolate sandwich cookie accompanied by a splash of milk pictured against a dark blue background, and the “Stoneo” logo mimics the Oreo logo, with both featuring white text in all caps with a gray drop shadow, set against a blue background that is outlined in a lighter shade of blue.

Imitating non-THC-containing food products often consumed by children through the use of advertising or labeling is

Life Leaf Medical CBD Center
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cc:

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