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RE: 674916

Dear Robert Waring:

This Commission (FTC) and the U.S. Food and Drug Administration (FDA) and the Federal

_____ in
November 2023, January 2024, 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 Dr. Blaze THC Delta-8
Slushers, Doweedos Delta-8 Chips, and Delta-8 Weedos 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
_____ in the United States.

_____. You can find specific information about how FDA
regulates cannabis-derived products at <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>.
FDA has observed a proliferation of products containing the cannabinoid, Delta-8 THC, and has

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 and chips) 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 Dr. Blaze THC Delta-8 Slushers, Doweedos Delta-8 Chips, and Delta-8 Weedos are both in forms that may be attractive to children and could easily be mistaken for traditional foods that are commonly consumed by children.

Adulterated Human Foods

According to your product labeling, your Dr. Blaze THC Delta-8 Slushers, Doweedos Delta-8 Chips, and Delta-8 Weedos are foods to which Delta-8 THC has been added.

As defined in section 201(s) of the Act (21 U.S.C. 321(s)), the term “food additive” refers to any substance the intended use of which results in it becoming a component of any food, unless the 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

¹ FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC (June 16, 2022) <https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc>

² Under section 201(s) of the Act (21 U.S.C. 321(s)), the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food, (2) pesticide chemicals, (3) color additives, (4) substances used in accordance with a “prior sanction” (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the Act, the Poultry Products Inspection Act, or the Meat Inspection Act), (5) new animal drugs, and (6) dietary ingredients in or intended for use in a dietary supplement.

for eligibility for classification of a food ingredient as GRAS. The use of a food substance may be GRAS based on either scientific procedures or, for a substance used in food before 1958, through experience based on common use in food (see 21 CFR 170.30).

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-8 THC in conventional food does not satisfy the criteria for GRAS status under 21 CFR 170.30.

FDA is not aware of any other exception to the food additive definition that would apply to Delta-8 THC for use as an ingredient in a conventional food. Therefore, Delta-8 THC added to a conventional food is a food additive under section 201(s) of the Act and is subject to the provisions of section 409 of the Act. Under section 409, a food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. Delta-8 THC is not approved for use in any conventional food. Food containing an unsafe food additive within the meaning of section 409 is adulterated within the meaning of section 402(a)(2)(C)(i) of the Act. Therefore, your Dr. Blaze THC Delta-8 Slushers, Doweedos Delta-8 Chips, and Delta-8 Weedos are adulterated within the meaning of section 402(a)(2)(C)(i) of the Act because they bear or contain an unsafe food additive. Introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the Act, 21 U.S.C. 331(a).

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

This letter notifies you of FDA's concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and injunction.

We also offer the following comment:

We note that your firm sells food products that contain cannabinoids other than Delta-8 THC. We know of no basis to conclude that any use in food of a cannabinoid, plant derived or otherwise, would be safe and lawful. For some cannabinoids, such as Delta-8 THC, the available data raise serious concerns about potential harm. For other cannabinoids, there is little or no available information concerning the safety of their use in food. No cannabinoid, plant derived or otherwise, is approved for any use in food as a food additive. Moreover, we know of

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

