WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Exclusive Hemp Farms
355 Maycock Road
Suite 8
Gilroy, CA 95050-7025 USA

Etienne-DuBois, LLC
Oshipt
8855 Strath Road
Henrico, VA 23231-0000 US

RE: 648877

Dear Ms. Etienne:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) and Federal Trade Commission (FTC) reviewed your websites at the Internet addresses www.exclusivehempfarms.com and www.oshipt.com in February 2023 and June 2023, respectively, and have determined that you take orders for various human products, which you represent as containing Delta-8 tetrahydrocannabinol (THC). Customers place orders for these products on Oshipt.com and receive the orders from Exclusive Hemp Farms (EHF). FDA has determined that your Oreo Stoneo – Medicated 500mg, Cannaa Banana Delta 8 - Rope Candy 600mg - 7 Flavors, Pot Tarts Strawberry 1000mg - Medicated, Tropical Sour Patch - Delta-8 500mg, Trips Ahoy Medicated – Real Chocolate Chip Cookies - 600mg Medicated, Trips Ahoy Medicated – Real Chocolate Chunky Cookies - 600mg Medicated, and Medicated Cheddar Snack Crackers 600mg – Medicated products are adulterated under section 402(a)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 342(a)(2)(C)(i), because they bear or contain an unsafe food additive. Furthermore, it is a prohibited act to introduce adulterated food into interstate commerce under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

As explained further below, introducing or delivering these products for introduction into interstate commerce violates the FD&C Act. You can find the FD&C Act and FDA regulations through links on FDA's home page at www.fda.gov. 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 recently expressed serious concerns about products containing Delta-8 THC that include: 1) Delta-8 THC products have not been evaluated or approved by FDA for safe use and may be marketed in ways that put the public health at risk; 2) FDA has received adverse event reports involving Delta-8 THC containing products; 3) Delta-8 THC has psychoactive and intoxicating effects; 4) FDA is concerned about the processes used to create the concentrations of Delta-8 THC claimed in the marketplace; and 5) FDA is concerned about Delta-8 THC products that may be consumed by children, as some packaging and labeling may appeal to children. 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, chips, and beverages) 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] As noted in the warning, the agency received over 125 adverse event reports from January 1, 2021, through May 31, 2022, related to children and adults who consumed edible products containing THC. Ten of the reports specifically mention the edible product to be a copycat of popular foods. Your Oreo Stoneo – Medicated 500mg, Cannaa Banana Delta 8 - Rope Candy 600mg - 7 Flavors, Pot Tarts Strawberry 1000mg - Medicated, Tropical Sour Patch - Delta-8 500mg, Trips Ahoy Medicated – Real Chocolate Chip Cookies - 600mg Medicated, Trips Ahoy Medicated – Real Chocolate Chunky Cookies - 600mg Medicated, and Medicated Cheddar Snack Crackers 600mg – Medicated 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 Oreo Stoneo – Medicated 500mg, Cannaa Banana Delta 8 - Rope Candy 600mg - 7 Flavors, Pot Tarts Strawberry 1000mg - Medicated, Tropical Sour Patch - Delta-8 500mg, Trips Ahoy Medicated – Real Chocolate Chip Cookies - 600mg Medicated, Trips Ahoy Medicated – Real Chocolate Chunky Cookies - 600mg Medicated, and Medicated Cheddar Snack Crackers 600mg – Medicated products are foods to which Delta-8 THC has been added. Furthermore, your Oreo Stoneo – Medicated 500mg is labeled with a Nutrition Facts panel which is more likely to be confused for a genuine food or snack product.

As defined in section 201(s) of the FD&C 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

[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

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 FD&C Act (21 U.S.C. 348(a)) and causes the food to be adulterated under section 402(a)(2)(C)(i) of the FD&C 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 FD&C 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 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 FD&C Act and is subject to the provisions of section 409 of the FD&C 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 FD&C Act. Therefore, your Oreo Stoneo – Medicated 500mg, Cannaa Banana Delta 8 - Rope Candy 600mg - 7 Flavors, Pot Tarts Strawberry 1000mg - Medicated, Tropical Sour Patch - Delta-8 500mg, Trips Ahoy Medicated – Real Chocolate Chip Cookies - 600mg Medicated, Trips Ahoy Medicated – Real Chocolate Chunky Cookies - 600mg Medicated, and Medicated

[2] Under section 201(s) of the FD&C 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 FD&C 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.

Cheddar Snack Crackers 600mg – Medicated products are adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C 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 FD&C 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.

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 FD&C Act, include your reasoning and any supporting information for our consideration.

Your response should be sent to CFSANResponse@fda.hhs.gov. Please include "CMS 648877" in the subject line of your email.

Unfair or Deceptive Marketing

In addition, the FTC has reviewed your online marketing of Delta-8 THC products. 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, you have marketed various Delta-8 THC products with an appearance and form similar to conventional foods and candies often consumed by children. For example, you have advertised Oreo Stoneo – Medicated 500mg in packaging resembling that for Nabisco Oreo Double Stuf chocolate cookies, using the same blue background, a red triangle in the upper lefthand corner reading "DABISCO" in the style of the Nabisco logo, and a depiction of a crème-filled chocolate sandwich cookie with a splash of milk. Also, you have marketed Medicated Cheddar Snack Crackers 600mg in packaging using the Cheez-It logo including a depiction of what appear to be Cheez-It crackers. Imitating non-THC-containing food products often consumed by children through the use of advertising or labeling is misleading. FTC Policy

Statement on Deception, 103 F.T.C. 174, 176 n.9 (1984) (appended to *Cliffdale Assocs., Inc.*, 103 F.T.C. 110 (1984)) (the nature, appearance, or intended use of a product may create an impression in the mind of the consumer, and it is deceptive if this impression is false and not corrected by the seller); 15 U.S.C. §§ 52, 55(a)(1) (under Section 12 of the FTC Act, which prohibits false advertisements for foods and drugs, the Commission must consider any consequences that may result from the use of the product under customary or usual conditions).

Children are at particular risk for mistakenly ingesting edible THC products imitating traditional foods because they are more likely to focus on similarities of product appearance and packaging, and less likely to notice or be able to comprehend labeling text. Ingesting edible cannabis products can result in serious health consequences in children.[3] Given the significant 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 with 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 -S
Digitally signed by Ann M. Oxenham -S
Date: 2023.06.28 16:46:41 -04'00'

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

Sincerely,

Serena Viswanathan

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission

[3] *See, e.g.*, Marit Tweet et al., *Pediatric Edible Cannabis Exposures and Acute Toxicity: 2017-2021*, Pediatrics 2023;151(2): e2022057761.