WARNING LETTER

Functional Remedies, LLC D/B/A Synchronicity Hemp Oil

MARCS-CMS 627208 — MARCH 28, 2022

Product:

Drugs

Recipient:

Andrew Campbell

Functional Remedies, LLC D/B/A Synchronicity Hemp Oil

331 S. 104th Street, Suite 210

Louisville, CO 80027

United States

hello@synchronicityhempoil.com (mailto:hello@synchronicityhempoil.com)

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

Federal Trade Commission

WARNING LETTER

RE: 627208

Date: March 28, 2022

RE: Unapproved and Misbranded Product Related to Coronavirus Disease 2019 (COVID-19)

This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address https://synchronicityhempoil.com/ on February 16, 2022, and March 1, 2022, respectively. The FDA has observed that your website offers Full-Spectrum Hemp Oil and cannabidiol (CBD) products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[2] In addition,

on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.[3] Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Some examples of the claims on your website that establish the intended use of your products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- "Hemp Oil has been shown to possibly reduce viral inflammation, known as a cytokines storm, which can be detrimental and even deadly to a person suffering from a viral infection, such as COVID-19." [from a November 24, 2020 blog post titled "Can Hemp Oil Combat Inflammation and Viruses?" on your website https://synchronicityhempoil.com/hemp-oil-to-treat-inflammation-andviruses/]
- "**Exciting Discoveries: CBD and COVID-19** Research released in May 2020 revealed fascinating findings about the potential effects of cannabis on the COVID-19 virus: 'Similar to other respiratory pathogens, SARS-CoV2 (COVID-19) is transmitted through respiratory droplets, with potential for aerosol and contact spread . . . ACE2 levels were in fact significantly down-regulated when specific strains of cannabis were introduced, supporting their theory that the anti-inflammatory properties of CBD could inhibit the virus's ability to successfully bind to a host. Cannabinoids may decrease the number of receptors available to the virus giving your body more of a chance to fight it." [from a November 24, 2020 blog post titled "Can Hemp Oil Combat Inflammation and Viruses?" on your website https://synchronicityhempoil.com/hemp-oil-to-treat-inflammation-and-viruses/]

You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19-related use for which they have not been approved by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act. **Within 48 hours, please send an email to COVID-19-Task-Force-CDER@fda.hhs.gov** describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction.

FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products (/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products). Once you have taken actions to address the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions.

This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, 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.

If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs may be detained or refused admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your product(s) referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States.

Please direct any inquiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov.

FTC Cease and Desist Demand: In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well- controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to $46,517 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b). Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov certifying that you have ceased making unsubstantiated claims for the products identified above. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,
/s/
Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,
/s/
Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission

---

1 As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).

2 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx (https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx).

3 Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/ (https://trumpwhitehouse.archives.gov/presidential-

actions/proclamationdeclaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/).

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

Delta 8 Hemp

MARCS-CMS 618368 — MAY 04, 2022

Delivery Method:

Via Email

Product:

Drugs
Food & Beverages

Recipient:

Delta 8 Hemp

1116 S Main Street
Los Angeles, CA 90015
United States

info@delta8cart.net (mailto:info@delta8cart.net)

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

WARNING LETTER

May 4, 2022

RE: # 618368

Dear Delta 8 Hemp:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address https://delta8thc.market/ in April 2022 and has determined that you take orders there for various human products, which you represent as containing Delta-8 tetrahydrocannabinol (THC). The claims on your website establish that your products, some of which are available in multiple varieties, "Delta 8 THC Distillate Oil," "Delta 8 THC Vape Cartridge," "Delta 8 THC Disposable Vape Pen," "Delta 8 THC Tincture," "Delta 8 Infused Gummies," and "Delta 8 Infused Sour Gummies" (hereinafter referred to as "Delta-8 THC products for humans"), are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a) and 331(d). Furthermore, these products are misbranded drugs under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1).

FDA has also determined that your "Delta 8 Infused Gummies" and "Delta 8 Infused Sour Gummies" products are adulterated under section 402(a)(2)(C)(i) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(i), because they bear or contain an unsafe food additive.

As explained further below, introducing or delivering these products for introduction into interstate commerce violates the FD&C Act. 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 (/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd).

Over the past several years, FDA has warned the public on various illegally marketed CBD-containing products. FDA has also observed a proliferation of products containing another 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 (/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.

Unapproved New Human Drugs

Based on a review of your websites, your Delta-8 THC products for humans are drugs under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or intended to affect the structure or any function of the body.

Examples of claims from your website https://delta8thc.market/ that provide evidence of the intended use of these products as drugs include, but may not be limited to, the following:

On your blog post titled, "3 Ways to Boost Your Immune System with Delta-8 THC":

- "Delta-8 THC can be used to suppress the immune response in your body. If a patient is suffering from autoimmune diseases, Delta-8 THC will offer some relief and support. Some of these diseases include lupus, HIV/AIDS, and multiple sclerosis."
- "Delta-8 THC prevents rapid cell growth while promoting cellular death . . . people who have a hyperactive immune system will gain significantly since such properties assist in the healing process."
- "If you have cancer, rheumatoid arthritis, and migraines, Delta-8 THC can help alleviate the pain because it has immunosuppressant properties."
- "[R]esearchers have currently noted that Delta-8 THC reduces inflammation, prevents autoimmune diseases, and offers pain relief."

On your blog post titled, "Does Delta-8 THC help to Reduce Anxiety?":

- "Where there are many benefits of Delta-8 THC, such as ways to boost your immune system with Delta-8 THC, some reason [*sic*] to try Delta-8 THC are as follows:
    - Substance Abuse Treatment"
- "Yes, Delta-8 THC does help to reduce anxiety."

On your webpage titled, "What is Delta 8 THC?":

- "In non-medical terms, researchers linked Delta 8-THC to anti-nausea (antiemetic), anti-anxiety (anxiolytic), and pain relief (analgesic) benefits, among other effects . . . It could also protect brain cells thanks to its neuroprotective effects."

- "The most notable benefits linked to Delta 8-THC include:
    - Help with pain and inflammation
    - Eliminate nausea in cancer patients"
- Posted on this page is your YouTube video titled "What is this Delta 8 Stuff?" which includes the text "Delta-8 is known to be successful in many cancer treatments."

Your Delta-8 THC products for humans are not generally recognized as safe and effective (GRASE) for their above referenced uses and, therefore, these products are "new drugs" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 355(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective. There are no FDA-approved applications in effect for any of the above-mentioned products.

Misbranded Human Drugs

Your Delta-8 THC products for humans are misbranded within the meaning of section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), in that their labeling fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended. (See 21 CFR 201.5.) Your Delta-8 THC products for humans are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners. Therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Under 21 CFR 201.100(c)(2) and 201.115, FDA-approved prescription drugs that bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson. However, your products are not exempt from the requirement that their labeling bear adequate directions for use because no FDA-approved applications are in effect for your products.

The introduction or delivery for introduction into interstate commerce of misbranded drugs violates section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Adulterated Human Foods

According to your product labeling, your "Delta 8 Infused Gummies" and "Delta 8 Infused Sour Gummies" products are foods to which Delta-8 THC has been added.

You should also be aware that, 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 its 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.[1]

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 your products 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 "Delta 8 Infused Gummies" and "Delta 8 Infused Sour Gummies" 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 these adulterated foods 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 our 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 correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. 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. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance by email to FDAADVISORY@fda.hhs.gov (mailto:FDAADVISORY@fda.hhs.gov).

Sincerely,

/S/
Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

/S/
Ann M. Oxenham
Director

Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

[1] 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.

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

Naturally Infused LLC

MARCS-CMS 628036 — NOVEMBER 16, 2022

Delivery Method:

Via Overnight Delivery

Product:

Animal & Veterinary
Drugs
Food & Beverages

Recipient:

Gaetano Venezia

Naturally Infused LLC

6813 State Road 54
New Port Richey, FL 34653-6019
United States

Guy@NaturallyInfused.com (mailto:Guy@NaturallyInfused.com)

Issuing Office:

Center for Food Safety and Applied Nutrition (CFSAN)

United States

Center for Drug Evaluation and Research
Center for Veterinary Medicine

WARNING LETTER

November 16, 2022

RE: # 628036

Dear Mr. Venezia:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.naturallyinfused.com in October 2022 and has determined that you take orders there for various human and animal products, which you represent as products containing cannabidiol (CBD) or Delta-8 tetrahydrocannabinol (THC). We have also reviewed your social media websites at https://www.instagram.com/naturallyinfusedcbd/ and at https://www.facebook.com/Naturally-Infused-CBD-CBG-335285106887519/; these websites direct consumers to your website www.naturallyinfused.com to purchase your products.

FDA has determined that your CBD Lollipops, CBD Infused Sugar, CBD Gummies, CBD Infused coffees, D8 THC Infused coffees, and Delta-8 THC Gummies products are adulterated under section 402(a)(2)(C)(i) of 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 your CBD Lollipops, CBD Infused Sugar, CBD Gummies, and CBD Infused coffees products into interstate commerce under section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll).

Further, the claims on your website and social media websites establish that all strengths and varieties of CBD Lollipops, CBD Infused Sugar, CBD Gummies, CBD Infused coffees, CBD Isolate in MCT Oil, CBD Plus CBG in MCT Oil, CBD/CBG/CBN Isolates in MCT Oil, CBD/CBG/CBN/Delta 8 THC, Full Spectrum Oil CBD, Roll & Rub CBD Oil, and Spray & Rub CBD (hereinafter referred to as "your CBD-containing products for humans") are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a) and 331(d). Furthermore, your CBD-containing products for humans are misbranded drugs under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1).

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 (//www.fda.gov). You can find specific information about how FDA regulates CBD at https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd (/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd).

Over the past several years, FDA has warned the public on various illegally marketed CBD-containing products. FDA has also observed a proliferation of products containing another 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.

As stated above, the Agency is particularly concerned that some of your products are in forms that are appealing to children. For example, your CBD Lollipops, CBD Gummies, and Delta-8 THC Gummies are in forms that would be attractive to children and could easily be mistaken for traditional foods that are commonly consumed by children. Furthermore, you market other products that consumers may confuse with traditional foods for humans, including CBD Infused Sugar and CBD and Delta-8 THC Infused coffees. Therefore, there is a risk that consumers of these products, including children, will unintentionally consume CBD or Delta-8 THC ingredients. Additionally, we note that the CBD coffee products appear to contain caffeine. Evidence suggests that CBD may affect caffeine metabolism and may increase and/or prolong caffeine's effects.

Your products have not been evaluated by the Agency for safety, effectiveness, and quality. As discussed below, CBD has been studied as a drug, and it is the active ingredient in the approved drug product Epidiolex. The use of untested drugs can have unpredictable and unintended consequences, especially in vulnerable populations, such as children. For example, children may be at greater risk for adverse reactions associated with certain drug products due to differences in the ability of children to absorb, metabolize, distribute, or excrete such drug products or their metabolites.

The Agency has also collected and analyzed samples of your CBD Lollipops and CBD Infused Sugar products and has confirmed the presence of cannabinoids in the products. We have particular safety concerns with the CBD Lollipops product, which was purchased from your website and did not have a label on the packaging indicating that the lollipops

contain CBD. A consumer, including a child, could easily mistake the product for a traditional lollipop candy.

301(ll) and Adulterated Human Foods

According to your product labeling, your CBD Lollipops, CBD Infused Sugar, CBD Gummies, and CBD Infused coffees products are foods to which CBD has been added.

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 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.[1]

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 which authorizes the use of CBD. We are not aware of any information to indicate that CBD is the subject of a prior sanction (see 21 CFR Part 181). Furthermore, we are not aware of any basis to conclude that CBD 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 CBD 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 CBD in food meets the criteria for GRAS status. Some of the available data raise serious concerns about potential harm from CBD. Our review of publicly available data associated with the one FDA-approved CBD drug, as well as our review of published scientific literature, identified potential for liver injury from CBD and potentially harmful interactions with certain drugs. In addition, studies in animals have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels, and impair sexual behavior in males. Therefore, based on our review, the use of CBD in your products 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 CBD for use as an ingredient in a conventional food. Therefore, CBD 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. CBD 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 CBD Lollipops, CBD Infused Sugar, CBD Gummies, and CBD Infused coffees 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 these adulterated foods into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Further, according to your product labeling, your D8 THC Infused coffees and Delta-8 THC Gummies are foods to which Delta-8 THC has been added.

There is no food additive regulation which 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 your products 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 D8 THC Infused coffees and Delta-8 THC Gummies 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 these adulterated foods into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

It is a prohibited act under section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll), to introduce or deliver for introduction into interstate commerce any food, including animal food, to which has been added a drug approved under section 505 of the FD&C Act or for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. Based on available evidence, FDA has concluded that the prohibition in section 301(ll) applies to CBD.[2] There is an exception if the substance was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted. However, based on the available evidence, FDA has concluded that this is not the case for CBD. FDA is not aware of any evidence that would call into question its current conclusion that section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll), prohibits the introduction into interstate commerce of any food to which CBD has been added, but you may present FDA with any evidence bearing on this issue.

According to your product labeling, your CBD Lollipops, CBD Infused Sugar, CBD Gummies, and CBD Infused coffees are foods to which CBD has been added. Therefore, the introduction or delivery for introduction into interstate commerce of these products is a prohibited act under section 301(ll) of the FD&C Act.

Unapproved New Human Drugs

Based on our review of your website and social media websites listed above, your CBD-containing products for humans are drugs under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or any function of the body.

Examples of claims observed on your website and social media websites that establish the intended use of your CBD-containing products for humans as drugs include, but may not be limited to, the following:

From your website https://naturallyinfused.com/articles.html, webpage titled, "Articles," that lists links to pages with articles and blog posts, including:

• A link to an article entitled, "A Primer About Cannabidiol and the Benefits of CBD," which contains claims such as, "CBD is a powerful anti-epileptic, anti-depressant . . . muscle relaxant, sedative . . ."
• A link to an article entitled, "CBD and Bipolar Disorder," which contains claims such as, "research suggests that certain cannabinoids found in marijuana, i.e. THC and CBD, may have significant mood-stabilizing properties that could be beneficial for patients with bipolar disorder. . . CBD seems to counter the psychoactive effects produced by high doses of THC and may also possess anti-anxiety, hypnotic and anticonvulsant properties of its own."

From your social media website https://www.facebook.com/Naturally-Infused-CBD-CBG-335285106887519/:

• August 20, 2021 post: "Recommended by primary care physicians, cardiologist [sic], chiropractors, pain management doctors and more! If you want help to stop taking opioids, stop on by! 6813 State Road 54 New Port Richey [the street address for your firm's retail store]" followed by an image of a store window displaying the text, "CBD."
• September 27, 2017 post: An image of a banner displaying the text, "Alzheimers [sic] – Anxiety . . . Autism – Auto Immune Disorder – Cancer – Depression – Diabetes – Epilepsy . . . NATURALLY INFUSED CBD . . . Spray & Rub . . . Roll & Rub . . . Tinctures . . . NATURALLYINFUSED.COM[,] Fibromyalgia – Glaucoma . . . M.S. . . . Psoriasis – Seizures"
• June 2, 2017 posts: Images of a T-shirt with the text "Got CBD?" on the front of the shirt and the following text on what appears to be the back of the shirt: "HAVE THESE? . . . Auto Immune Disorder . . . M.S. . . . Cancer . . . Depression . . . Psoriasis . . . Epilepsy . . . Seizures . . . Fibromyalgia . . . Go To: NaturallyInfused.com"[3]

Your CBD-containing products for humans are not generally recognized as safe and effective for their above referenced uses and, therefore, these products are "new drugs" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective. There are no FDA-approved applications in effect for any of the above-mentioned CBD-containing products for humans.

Misbranded Human Drugs

Your CBD-containing products for humans are also misbranded within the meaning of section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), in that their labeling fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended. See 21 CFR 201.5. The aforementioned products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. FDA-approved prescription drugs that bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson. However, your products are not exempt from the requirement that their labeling bear adequate directions for use, under 21 CFR 201.100(c)(2) and 201.115, because no FDA-approved applications are in effect for them. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates 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 our 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.

Additionally, we have the following comment:

We are concerned that it appears your firm is marketing the following products intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals: Canine and Feline Comfort, CBD Plus CBG in organic MCT Oil, and CBD/CBG/CBN Isolates in organic MCT Oil. These products are marketed on your social media website for intended uses including, but not limited to, the treatment of anxiety, seizures, and pain. There are FDA approved animal drugs to treat these conditions. If not treated appropriately, these conditions can have detrimental health and welfare consequences for animals.

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 628036" in the subject line of your email.

Sincerely,
/S/

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

/S/

Carolyn E. Becker
Director
Office of Unapproved Drugs and Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

/S/

Neal Bataller
Director
Division of Drug Compliance
Office of Surveillance & Compliance
Center for Veterinary Medicine
Food and Drug Administration

---

1 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.

2 CBD is the active ingredient in the approved drug product Epidiolex. Furthermore, the existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex. (See **GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome**). FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under 21 CFR 312.2, unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

3 Your January 29, 2020 post on your social media website at https://www.instagram.com/p/B7576EJALfM/ contains similar claims.

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

GCHNC LLC dba Hemp XR/Gate City Hemp dba Hemp XR/Allaziya Enterprises, LLC dba Hemp XR

MARCS-CMS 656057 — SEPTEMBER 28, 2023

Delivery Method:

Via Overnight Delivery

Product:

Food & Beverages

Recipient:

Alaa Odeh Mahmoud Hamed and Abdulraouf B. Allamandani

Registered Agents

GCHNC LLC dba Hemp XR/Gate City Hemp dba Hemp XR/Allaziya Enterprises, LLC dba Hemp XR

2138-B Lawndale Dr.

Greensboro, NC 27408

United States

hempxr@gmail.com (mailto:hempxr@gmail.com)

Issuing Office:

Center for Food Safety and Applied Nutrition (CFSAN)

United States

WARNING LETTER

September 28, 2023

3741 Battleground Ave Ste C

Greensboro, NC 27410

RE: # 656057

Dear Alaa Odeh Mahmoud Hamed and Abdulraouf B. Allamandani:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address https://hemp-xr.com/ in September 2023 and has determined that you take orders there for various products, which you represent as containing Delta-8 tetrahydrocannabinol (THC) or cannabidiol (CBD).

FDA has determined that your Far Out Candy 500MG Delta 8 Cookies, Not Ya Son's Weed Bakedies Delta 8 THC 600MG Crispy Bites, Hemp XR Delta 8 Stoner Candy Gummies (including Crawlers, Fruit Smashers, Magic Marbles, and Stoney Headz Sour), Lava Rocks 250 MG Delta 8, Delta 8 Rainbow Rope, Pharma Delta 8 Gummies, Hemp XR Delta 8 Honey

500 MG, and Hemp XR CBD Honey 500 MG 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. 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). Furthermore, it is a prohibited act to introduce your Hemp XR CBD Honey 500 MG product into interstate commerce under section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll).

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.

Over the past several years, FDA has warned the public on various illegally marketed CBD-containing products. FDA has also observed a proliferation of products containing another 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.

Adulterated Human Foods

According to your product labeling, your Far Out Candy 500MG Delta 8 Cookies, Not Ya Son's Weed Bakedies Delta 8 THC 600MG Crispy Bites, Hemp XR Delta 8 Stoner Candy Gummies (including Crawlers, Fruit Smashers, Magic Marbles, and Stoney Headz Sour), Lava Rocks 250 MG Delta 8, Delta 8 Rainbow Rope, Pharma Delta 8 Gummies, and Hemp XR Delta 8 Honey 500 MG products are foods to which Delta-8 THC has been added.

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 its 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.[1]

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 your products 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 Far Out Candy 500MG Delta 8 Cookies, Not Ya Son's Weed Bakedies Delta 8 THC 600MG Crispy Bites, Hemp XR Delta 8 Stoner Candy Gummies (including Crawlers, Fruit Smashers, Magic Marbles, and Stoney Headz Sour), Lava Rocks 250 MG Delta 8, Delta 8 Rainbow Rope, Pharma Delta 8 Gummies, and Hemp XR Delta 8 Honey 500 MG 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 these adulterated foods into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Furthermore, according to your product labeling, your Hemp XR CBD Honey 500 MG is a food to which CBD has been added.

There is no food additive regulation which authorizes the use of CBD. We are not aware of any information to indicate that CBD is the subject of a prior sanction (see 21 CFR Part 181). Furthermore, we are not aware of any basis to conclude that CBD 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 CBD 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 CBD in food meets the criteria for GRAS status. Some of the available data raise serious concerns about potential harm from CBD. Our review of publicly available data associated with the one FDA-approved CBD drug, as well as our review of published scientific literature, identified potential for liver injury from CBD and potentially harmful interactions with certain drugs. In addition, studies in animals have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels, and impair sexual behavior in males. Therefore, based on our review, the use of CBD in your products 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 CBD for use as an ingredient in a conventional food. Therefore, CBD 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. CBD 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 Hemp XR CBD Honey 500 MG product is adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act because it bears or contains an unsafe food additive. Introduction of this adulterated food into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

In addition, it is a prohibited act under section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll), to introduce or deliver for introduction into interstate commerce any food, including animal food, to which has been added a drug approved under section 505 of the FD&C Act or for which substantial clinical investigations have been instituted and for which the

existence of such investigations has been made public. Based on available evidence, FDA has concluded that the prohibition in section 301(ll) applies to CBD.[2] There is an exception if the substance was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted. However, based on the available evidence, FDA has concluded that this is not the case for CBD. FDA is not aware of any evidence that would call into question its current conclusion that section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll), prohibits the introduction into interstate commerce of any food to which CBD has been added, but you may present FDA with any evidence bearing on this issue.

As stated above, according to your product labeling, your Hemp XR CBD Honey 500 MG product is a food to which CBD has been added. Therefore, the introduction or delivery for introduction into interstate commerce of this product is a prohibited act under section 301(ll) of the FD&C Act.

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 our 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 action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. 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 the United States Food and Drug Administration at CFSANResponse@fda.hhs.gov. Please include "CMS 656057" in the subject line of your email.

Sincerely,
/S/

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

---

[1] 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.

[2] CBD is the active ingredient in the approved drug product Epidiolex. Furthermore, the existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex. (See GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome). FDA considers a

substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under 21 CFR 312.2, unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

Earthly Hemps

MARCS-CMS 674916 — JULY 15, 2024

Delivery Method:

Via Overnight Delivery
Return Receipt Requested

Product:

Food & Beverages

Recipient:

Robert Waring

Earthly Hemps

1827 SE 21st St

Cape Coral, FL 33990

United States

(b)(6) (mailto:(b)(6))

sales@earthlyhemps.com (mailto:sales@earthlyhemps.com)

Issuing Office:

Center for Food Safety and Applied Nutrition (CFSAN)

United States

Federal Trade Commission

United States

WARNING LETTER

RE: 674916

Dear Robert Waring:

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 earthlyhemps.com 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 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. You can find the 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 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 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 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 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 674916" in the subject line of your email.

Unfair or Deceptive Marketing

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 Slushers THC-infused fruit snacks are in sold in packaging featuring multiple streams of brightly-colored liquids that resembles packaging for other fruit snacks commonly consumed by children. Your Doweedos chips are sold in packaging prominently depicting a cartoon anthropomorphized orange tortilla chip, and your Weedos are sold in packaging prominently featuring a depiction of the cheese snacks that are identical in appearance to that of Frito-Lay's Flamin' Hot Cheetos. The apparent refence to Flamin' Hot Cheetos is underscored with the use of a stylized "Weedos" logo on the packaging that uses the same font, color scheme, and overall graphical style as that of Flamin' Hot Cheetos.

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

Sincerely,

/S/

Serena Viswanathan

Associate Director

Division of Advertising Practices

Federal Trade Commission

Cc:

contact@privacyprotect.org

---

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.

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

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

Mary Jane's Bakery Co. LLC

MARCS-CMS 678010 — JULY 15, 2024

Delivery Method:

Via Overnight Delivery
Return Receipt Requested

Product:

Food & Beverages

Recipient:

Michael A Callahan

Mary Jane's Bakery Co. LLC

175 NW 14th Street
Miami, FL 33136
United States

support@maryjane'sbakery.com (mailto:support@maryjane'sbakery.com)

info@miamirave.com (mailto:info@miamirave.com)

Issuing Office:

Center for Food Safety and Applied Nutrition (CFSAN)

United States

Federal Trade Commission

United States

WARNING LETTER

Miami Rave LLC
6120 NW 27th Ave.
Miami, FL 33142

RE: 678010

Dear Mr. Callahan,

This letter is to advise you that the U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your websites at the Internet addresses 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).

As explained further below, introducing or delivering these products for introduction into interstate commerce violates the Act. You can find the 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 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 (candy, chips, and cookies) 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 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: 1,000 mg Delta-8 THC products are all 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 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: 1,000 mg Delta-8 THC are products 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 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 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 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 our 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 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 678010" in the subject line of your email.

Unfair or Deceptive Marketing

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 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 Sour Gummy Bears are sold in a package that is in the shape of a gummy bear and that further depicts multiple smaller gummy bears.

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

Sincerely,
/S/
Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission

cc:
Squarespace Domains II LLC
email@squarespace.com

Netregistry Wholesale Pty Ltd.
email@melbourneit.com.au

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.

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

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

Life Leaf Medical CBD Center

MARCS-CMS 674917 — JULY 15, 2024

Delivery Method:

Via Overnight Delivery
Return Receipt Requested

Product:

Food & Beverages

Recipient:

Spencer Willis

Life Leaf Medical CBD Center

11871 Plaza Dr. Unit 4
Murrells Inlet, SC 29576-7450
United States

wordpress@lifeleafmedical.com (mailto:wordpress@lifeleafmedical.com)

lifeleaf@sccoast.net (mailto:lifeleaf@sccoast.net)

Issuing Office:

Center for Food Safety and Applied Nutrition (CFSAN)

United States

Federal Trade Commission

United States

WARNING LETTER

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 Delta-8 THC Nerd Ropes (various flavors), Stoneos Delta-8 Cookies, and Delta-8 Cereal Treats 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. You can find the 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 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, 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 Delta-8 THC Nerd Ropes (various flavors), Stoneos Delta-8 Cookies, and Delta-8 Cereal Treats are 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 Delta-8 THC Nerd Ropes (various flavors), Stoneos Delta-8 Cookies, and Delta-8 Cereal Treats 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 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 Delta-8 THC Nerd Ropes (various flavors), Stoneos Delta-8 Cookies, and Delta-8 Cereal Treats 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 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.

Unfair or Deceptive Marketing

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 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 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,
/S/
Ann M. Oxenham
Director

Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Sincerely,
/S/
Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission

---

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.

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

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

Grow God, LLC

MARCS-CMS 674690 — JULY 15, 2024

Delivery Method:

Via Overnight Delivery
Return Receipt Requested

Product:

Food & Beverages

Recipient:

Jamiel Gustafson and Rhonda V. Edior-Gustafson

Grow God, LLC

5792 Dogwood Street
San Bernadino, CA 92404-7211
United States

Growgod.orders@gmail.com (mailto:Growgod.orders@gmail.com)

Issuing Office:

Center for Food Safety and Applied Nutrition (CFSAN)

United States

WARNING LETTER

RE: 674690

Dear Mr. Gustafson and Mrs. Edior-Gustafson:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address growgod.org in February and March 2024, and has determined that you take orders there for various food products, which you represent as containing Delta-8 tetrahydrocannabinol (THC). FDA has determined that your Medicated Funyuns – GrowGod™ Delta-8, Doritos – GrowGod™ Delta-8, Infused Gushers – GrowGod™ Delta-8, and Cheetos Flamin' Hot Crunchy – GrowGod™ Delta-8 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).

As explained further below, introducing or delivering these products for introduction into interstate commerce violates the Act. You can find the 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 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 (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 Medicated Funyuns – GrowGod™ Delta-8, Doritos – GrowGod™ Delta-8, Infused Gushers – GrowGod™ Delta-8, and Cheetos Flamin' Hot Crunchy – GrowGod™ Delta-8 products are all 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 Medicated Funyuns – GrowGod™ Delta-8, Doritos – GrowGod™ Delta-8, Infused Gushers – GrowGod™ Delta-8, and Cheetos Flamin' Hot Crunchy – GrowGod™ Delta-8 products 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 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 Medicated Funyuns – GrowGod™ Delta-8, Doritos – GrowGod™ Delta-8, Infused Gushers – GrowGod™ Delta-8, and Cheetos Flamin' Hot Crunchy – GrowGod™ Delta-8 products 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 our 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 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 674690" in the subject line of your email.

Sincerely,
/S/
Ann M. Oxenham

Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

cc:
Jamiel Gustafson
Rhonda V. Edior-Gustafson
GrowGod LLC
3400 Cottage Way, Suite G2
Sacramento, CA 95825-1474

---

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.

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

Shamrockshrooms.com

MARCS-CMS 675517 — JULY 15, 2024

Delivery Method:

Via Email

Product:

Food & Beverages

Recipient:

Shamrockshrooms.com

United States

Shamrockshrooms.com (mailto:Shamrockshrooms.com)

shamrockshrooms@gmail.com (mailto:shamrockshrooms@gmail.com)

checkla2020@gmail.com (mailto:checkla2020@gmail.com)

Issuing Office:

Center for Food Safety and Applied Nutrition (CFSAN)

United States

Federal Trade Commission

United States

WARNING LETTER

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 in 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. You can find the 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 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) 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 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 and could easily be mistaken for traditional foods that are commonly consumed by children.

Adulterated Human Foods

According to your product labeling, your Errlli Delta-8 THC Gummy Sharks, Errlli Delta-8 THC Sour Brite Crawlers, Errlli Delta-8 THC Sour Glowworms, 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 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 Errlli Delta- 8 THC Gummy Sharks, Errlli Delta-8 THC Sour Brite Crawlers, and Errlli Delta-8 THC Sour Glowworms 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 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 675517" in the subject line of your email.

Unfair or Deceptive Marketing

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 various Delta-8 THC products have an appearance and form similar to candy often consumed by children. All of your Errlli Delta-8 THC gummy products are sold in packaging that resembles that for Trolli gummy candies, including the use of the same puffy font for "Errlli" that is used in the Trolli logo. The package design for your Errlli Sour Brite Crawlers is nearly identical to that for Trolli Sour Brite Crawlers, including the use of a mottled blue background with solid black at the top and bottom, the depiction of multi-colored gummy worms, the identical font and similar color scheme used for the product name "SOUR BRITE Crawlers," and the identical position of the clear window that allows viewing of the package contents. The packaging for all three of your Errlli Delta-8 gummy products includes a clear window on the front that allows viewing of the gummies inside.

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

Sincerely,
/S/
Serena Viswanathan

Associate Director
Division of Advertising Practices
Federal Trade Commission

Cc:
Domains by Proxy, Inc.
14455 Hayden Rd.
Scottsdale, AZ 85260-6993

GoDaddy, Inc.
2155 GoDaddy Way
Tempe, AZ 85284-3409

---

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.

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

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

Hippy Mood

MARCS-CMS 677031 — JULY 15, 2024

Delivery Method:

Via Overnight Delivery
Return Receipt Requested

Product:

Food & Beverages

Recipient:

Emmett Hill and Amy L. Romejko

Hippy Mood

922 Woodbourne Rd, #184
Levittown, PA 19057
United States

Hippymoods@gmail.com (mailto:Hippymoods@gmail.com)

Issuing Office:

Center for Food Safety and Applied Nutrition (CFSAN)

United States

Federal Trade Commission

United States

WARNING LETTER

RE: 677031

Dear Mr. Hill and Ms. Romejko:

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.hippymood.com in January, March 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 Slushers Delta-8 Candy, Chuckles Peach Rings Delta-8 Candy, Rainbow Ropes Delta-8 Candy, Doweedos Delta-8 Edible Chips, Rainbow Rings Delta-8, Chocolate Balls Delta-8 Cereal, Cookie Cat Crunch Delta-8 Cereal, Frutti Rocks Delta-8 Cereal, and Berry Boss Delta 8 Cereal 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).

As explained further below, introducing or delivering these products for introduction into interstate commerce violates the Act. You can find the 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 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 (candy, chips, and cereals) 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 Slushers Delta-8 Candy, Chuckles Peach Rings Delta-8 Candy, Rainbow Ropes Delta-8 Candy, Doweedos Delta-8 Edible Chips, Rainbow Rings Delta-8 Cereal, Chocolate Balls Delta-8 Cereal, Cookie Cat Crunch Delta-8 Cereal, Frutti Rocks Delta-8 Cereal, and Berry Boss Delta -8 Cereal products are all 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 Slushers Delta-8 Candy, Chuckles Peach Rings Delta-8 Candy, Rainbow Ropes Delta-8 Candy, Doweedos Delta-8 Edible Chips, Rainbow Rings Delta-8 Cereal, Chocolate Balls Delta-8 Cereal, Cookie Cat Crunch Delta-8 Cereal, Frutti Rocks Delta-8 Cereal, and Berry Boss Delta-8 Cereal products 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 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 Slushers Delta-8 Candy, Chuckles Peach Rings Delta-8 Candy, Rainbow Ropes Delta-8 Candy, Doweedos Delta-8 Edible Chips, Rainbow Rings Delta-8 Cereal, Chocolate Balls Delta-8 Cereal, Cookie Cat Crunch Delta-8 Cereal, Frutti Rocks Delta-8 Cereal, and Berry Boss Delta-8 Cereal products 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.

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 eligibility for GRAS status.

This letter notifies you of our 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 Act, include your reasoning and any supporting information for our consideration.

Your response should be sent to CFSANResponse@fda.hhs.gov. Please include "CMS 677031" in the subject line of your email.

Unfair or Deceptive Marketing

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 various Delta-8 THC cereal products – Berry Boss, Chocolate Balls, Cookie Cat Crunch, Frutti Rocks, and Rainbow Rings – are sold in packing that uses color schemes and other graphical elements causing them to resemble packaging for popular children's cereals. For example, the Rainbow Rings Delta 8 Cereal package features a cartoon toucan on a red background, depicts ring-shaped cereal in multiple colors, and displays the name of the product all capital letters in a white font, with a piece of colored cereal substituting for the letter "O," which are all elements that are also present in the packaging for Kellogg's Froot Loops cereal. Likewise, the packaging for your Berry Boss Delta 8 product has a yellow background, depicts cereal that appears similar to Cap'n Crunch Crunch Berries (yellow pillow-shaped cereal mixed with larger round pink, green, and blue cereal pieces), features a cartoon character wearing a blue bicorne hat similar in design to that worn by the Cap'n Crunch mascot, and also displays the name of the product in a similar color scheme and style to that of Cap'n Crunch's Crunch Berries (with the first word in white lettering, the second word in red lettering, and both words set against a blue background). Packaging for other Delta-8 THC products you sell include clear plastic windows that make it possible for children to view their contents, which are visually indistinguishable from conventional candies (including Chuckle Peach Rings and Rainbow Ropes), and/or include graphical elements that imitate conventional foods commonly consumed by children or that are otherwise appealing to children (such as the graphical elements that make the packaging for Dr. Blaze Gummies resemble that for Fruit Gushers fruit snacks, or the anthropomorphic orange tortilla chip on the Doweedos package).

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

Sincerely,
/S/
Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission

---

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.

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

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

FDA NEWS RELEASE

FDA, FTC Continue Joint Effort to Protect Consumers Against Companies Illegally Selling Copycat Delta-8 THC Food Products

FDA, FTC Issue Warning Letters to Companies Selling Food Products Containing Delta-8 THC That Mimic Chips, Candies and Snacks from Popular National Brands

For Immediate Release:

July 16, 2024

Español (/news-events/press-announcements/la-fda-y-la-ftc-continuan-trabajando-juntas-para-proteger-los-consumidores-contra-las-companias-que)

Today, the U.S. Food and Drug Administration and the Federal Trade Commission (FTC) issued warning letters to five companies for illegally selling copycat food products containing delta-8 THC and introducing them into the marketplace in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The warning letters were issued to: Hippy Mood (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hippy-mood-677031-07152024), Earthly Hemps (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/earthly-hemps-674916-07152024), Shamrockshrooms.com (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/shamrockshroomscom-675517-07152024), Mary Janes Bakery Co. LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mary-janes-bakery-co-llc-678010-07152024) and Life Leaf Medical CBD Center (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/life-leaf-medical-cbd-center-674917-07152024). The FDA also issued a warning letter independently to the company GrowGod LLC (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/grow-god-llc-674690-07152024) for the same FD&C Act violations.

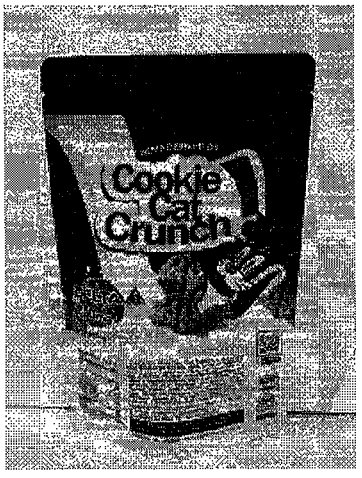
These warnings serve as part of the FDA and FTC's ongoing joint effort to take action against companies selling illegal copycat food products containing delta-8 THC. In July 2023 (/news-events/press-announcements/fda-ftc-warn-six-companies-illegally-selling-copycat-food-products-containing-delta-8-thc), the two agencies worked together to warn six other companies for selling edible food products containing delta-8 THC in packaging that could easily be confused for foods sold by popular national brands. All six of those companies no longer have such products in stock.

"Inadequate or confusing labeling can result in children or unsuspecting adults consuming products with strong resemblance to popular snacks and candies that contain delta-8 THC without realizing it," said FDA Principal Deputy Commissioner Namandjé Bumpus, Ph.D. "As accidental ingestion and/or overconsumption of delta-8 THC containing products could pose considerable health risks, the companies who sell these illegal products are demonstrating complete neglect for consumer safety. The FDA will continue to work to safeguard the health and safety of U.S. consumers by monitoring the marketplace and taking action when companies sell products that present a threat to public health."

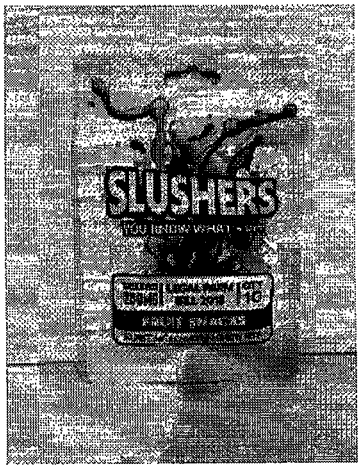
In June 2022, the FDA warned consumers (/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc) about children accidentally ingesting food products containing THC. From Jan. 1, 2021, to Dec. 31, 2023, the FDA received over 300 adverse event reports involving children and adults who consumed delta-8 THC products. Nearly half of these reports involved hospitalization or emergency department visits, and approximately two-thirds of these adverse events followed ingestion of delta-8 THC-containing food products such as candy or brownies. Adverse events included, but were not limited to, hallucinations, vomiting, tremor, anxiety, dizziness, confusion, and loss of consciousness.

Copycat food products containing delta-8 THC are particularly concerning to the FDA as they are extremely easy to purchase and are often available to youth. The FDA is also concerned about the processes used to synthesize delta-8 THC, as impurities or variations in composition can result in products that may be harmful or have unpredictable effects on consumers.

In addition, packaging that is almost indistinguishable from many popular snacks can be confusing for consumers. Several of the companies warned today illegally sell copycat food products containing delta-8 THC, including chips, cookies, gummies or other snacks that mimic well-known snack food brands by using similar brand names, logos, or pictures on packaging that consumers, especially children, may confuse with traditional foods. See below:



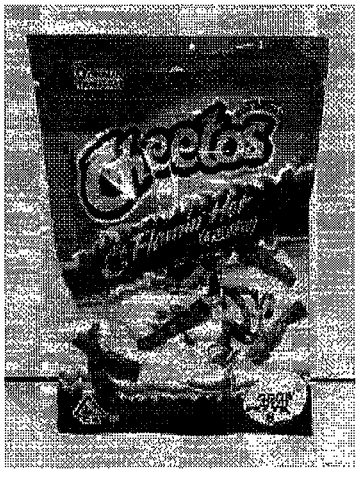
Hippy Mood "Cookie Cat Crunch"



Earthy Hemps "Slushers"

Mary Jane's Bakery Co. LLC "Infused Sour Slizzles"

Life Leaf Medical CBD Center "Double Stuff Stoneo"



GrowGod LLC "Flamin Hot Cheetos"

"Companies that market and sell edible THC products that are easily mistaken for snacks and candy are not only acting illegally, but they are also putting the health of young children at risk," said Samuel Levine, director of the FTC's Bureau of Consumer Protection. "Those that prioritize profits in front of children's safety are at serious risk of legal action."

The FDA encourages health care providers and consumers to report adverse reactions associated with FDA-regulated products to the agency using MedWatch (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program) or the Safety Reporting Portal (https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx?sid=f6de845d-05b6-4d76-86dd-93bf46dbd809).

The FDA has requested written responses from the companies within 15 working days stating how they will address these violations and prevent their recurrence. Failure to promptly address the violations may result in legal action, including product seizure and/or injunction.

Related Information

- FDA, FTC Warn Six Companies for Illegally Selling Copycat Food Products Containing Delta-8 THC (https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-companies-illegally-selling-cbd-and-delta-8-thc-products)
- FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products (https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-companies-illegally-selling-cbd-and-delta-8-thc-products)
- FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC (https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc)
- FDA Warns Companies for Illegally Selling Food and Beverage Products that Contain CBD (https://www.fda.gov/food/cfsan-constituent-updates/fda-warns-companies-illegally-selling-food-and-beverage-products-contain-cbd)
- FDA Warns Companies Illegally Selling CBD Products (https://www.fda.gov/news-events/press-announcements/fda-warns-companies-illegally-selling-cbd-products)
- FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) (https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd)

###

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Inquiries

Media:

Courtney Rhodes (mailto:Courtney.Rhodes@fda.hhs.gov)

202-281-5237

Consumer:

888-INFO-FDA