



## **WARNING LETTER**

### **VIA OVERNIGHT DELIVERY RETURN RECEIPT REQUESTED**

Radiant Hoang  
Delta Munchies LLC  
1100 Hope Street, Apt. 1510  
Los Angeles, CA 90015-2193  
[Contact@deltamunchies.com](mailto:Contact@deltamunchies.com)

RE: 656322

Dear Mr. Hoang:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) and Federal Trade Commission (FTC) reviewed your website at the Internet address [www.deltamunchies.com](http://www.deltamunchies.com) in March 2023 and June 2023, respectively, and have determined that you take orders there for various human products, which you represent as containing Delta-8 tetrahydrocannabinol (THC). FDA has determined that your Sour Worms – 625mg Delta-8 THC, Gummy Bears – 450mg Delta-8 THC, Strawberry Sour Belts – 3000mg Delta-8 THC, Peach Rings – 450mg Delta-8 THC, Berry Blue Sour Belts – 3000mg Delta-8 THC, Green Apple Sour Belts – 3000mg Delta-8 THC, Watermelon Gummies – 450mg Delta-8 THC, and Sour Bites – 450mg Delta-8 THC products are adulterated under section 402(a)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 342(a)(2)(C)(i), because they bear or contain an unsafe food additive. Furthermore, it is a prohibited act to introduce adulterated food into interstate commerce under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

As explained further below, introducing or delivering these products for introduction into interstate commerce violates the FD&C Act. You can find the FD&C Act and FDA regulations through links on FDA's home page at [www.fda.gov](http://www.fda.gov). You can find specific information about how FDA regulates cannabis-derived products at <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>.

FDA has observed a proliferation of products containing the cannabinoid, Delta-8 THC, and has recently expressed serious concerns about products containing Delta-8 THC that include: 1) Delta-8 THC products have not been evaluated or approved by FDA for safe use and may be marketed in ways that put the public health at risk; 2) FDA has received adverse event reports involving Delta-8 THC containing products; 3) Delta-8 THC has psychoactive and intoxicating effects; 4) FDA is concerned about the processes used to create the concentrations of Delta-8



section 409(a) of the FD&C Act (21 U.S.C. 348(a)) and causes the food to be adulterated under section 402(a)(2)(C)(i) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(i). Introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

There is no food additive regulation that authorizes the use of Delta-8 THC. We are not aware of any information to indicate that Delta-8 THC is the subject of a prior sanction (see 21 CFR Part 181). Furthermore, we are not aware of any basis to conclude that Delta-8 THC is GRAS for use in conventional foods. FDA's regulations in 21 CFR 170.30(a)-(c) describe the criteria for eligibility for classification of a food ingredient as GRAS. The use of a food substance may be GRAS based on either scientific procedures or, for a substance used in food before 1958, through experience based on common use in food (see 21 CFR 170.30).

We know of no basis for general recognition of safety for Delta-8 THC based either on scientific procedures or common use in food prior to January 1, 1958. Based on our review of published, scientific literature, existing data and information do not provide an adequate basis to conclude that the use of Delta-8 THC in food meets the criteria for GRAS status. Some of the available data raise serious concerns about potential harm from Delta-8 THC. Our review of published scientific literature identified potential for adverse effects on the central nervous and cardiopulmonary systems. In addition, studies in animals have suggested that gestational exposure to Delta-8 THC can interfere with neurodevelopment. Therefore, based on our review, the use of Delta-8 THC in conventional food does not satisfy the criteria for GRAS status under 21 CFR 170.30.

FDA is not aware of any other exception to the food additive definition that would apply to Delta-8 THC for use as an ingredient in a conventional food. Therefore, Delta-8 THC added to a conventional food is a food additive under section 201(s) of the FD&C Act and is subject to the provisions of section 409 of the FD&C Act. Under section 409, a food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. Delta-8 THC is not approved for use in any conventional food. Food containing an unsafe food additive within the meaning of section 409 is adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act. Therefore, your Sour Worms – 625mg Delta-8 THC, Gummy Bears – 450mg Delta-8 THC, Strawberry Sour Belts – 3000mg Delta-8 THC, Peach Rings – 450mg Delta-8 THC, Berry Blue Sour Belts – 3000mg Delta-8 THC, Green Apple Sour Belts – 3000mg Delta-8 THC, Watermelon Gummies – 450mg Delta-8 THC, and Sour Bites – 450mg Delta-8 THC products are adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act because they bear or contain an unsafe food additive. Introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

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



