



WARNING LETTER

**VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED**

Cindy Barton
The Haunted Vapor Room
33 Munsonhurst Road
Franklin, NJ 07416

RE: 648878

Dear Mrs. Barton:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) and Federal

[tetrahydrocannabinol-delta-8-thc](#). This letter is to inform you

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 Rope 500mg Delta 8 Nerds Candy, Medicated Dope Rope Bites, Packwoods x Coned Delta-8 Edible Cones – 600mg, Cake 500mg Delta 8 Gummy Pack, and Candy's D8 Chocolate Bars 500mg products are adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act because they bear or contain an unsafe food additive. Introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

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

This letter notifies you of FDA's concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal ac

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 648878” 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 Unfairne

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.