

The U.S. Food and Drug Administration's (FDA) Intergovernmental Affairs (IGA) team would like to share the following important information with you.

Today, FDA and the Federal Trade Commission issued warning letters to six companies for illegally selling copycat food products containing Delta-8 tetrahydrocannabinol, also known as delta-8 THC. These products can easily be mistaken for traditional foods like chips, cookies, candy, gummies or other snack food items. The FDA is concerned that these products can be accidentally ingested by consumers, including children, or taken in higher doses than intended. The warning letters were issued to: Delta Munchies, Dr. Smoke, LLC (also known as Dr. S, LLC), Exclusive Hemp Farms/Oshipt, Nikte's Wholesale, LLC, North Carolina Hemp Exchange, LLC and The Haunted Vapor Room.

"Children are more vulnerable than adults to the effects of THC, with many who have been sickened and even hospitalized after eating 'edibles' containing it. That's why we're issuing warnings to several companies selling copycat food products containing delta-8 THC, which can be easily mistaken for popular foods that are appealing to children and can make it easy for a young child to ingest in very high doses without realizing it," said Janet Woodcock, M.D., Principal Deputy Commissioner, FDA. "The products we are warning against intentionally mimic well-known snack food brands by using similar brand names, logos, or pictures on packaging, that consumers, especially children, may confuse with traditional snack foods. We're also concerned that adults could unintentionally take them or take a higher dose than expected and suffer serious consequences."

These warning letters outline violations of the Federal Food, Drug, and Cosmetic Act related to adding delta-8 THC to conventional foods. FDA has requested written responses from the six companies that received warning letters 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.

FDA's <u>Press Release</u> and links to additional information, along with my contact information, are below. FDA's IGA team is here to assist state/local/territorial/tribal officials, including the national associations representing them, on FDA policy-related matters. If you have any questions, please let me know if I can assist you further.

Best regards,

Ruth G. Watson, J.D.

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FDA, FTC Warn Six Companies for Illegally Selling Copycat Food Products Containing Delta-8 THC

Today, the U.S. Food and Drug Administration and the Federal Trade Commission issued warning letters to six companies for illegally selling copycat food products containing Delta-8 tetrahydrocannabinol, also known as delta-8 THC. These products can easily be mistaken for traditional foods like chips, cookies, candy, gummies or other snack food items. The FDA is concerned that these products can be accidentally ingested by consumers, including children, or taken in higher doses than intended. The warning letters were issued to: Delta Munchies, Dr. Smoke, LLC (also known as Dr. S, LLC), Exclusive Hemp Farms/Oshipt, Nikte's Wholesale, LLC, <a href="North Carolina Hemp Exchange, LLC and The Haunted Vapor Room.

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Delta-8 THC is a substance found in the Cannabis sativa plant, of which marijuana and hemp are two varieties. It has psychoactive and intoxicating effects that may be dangerous to consumers and it has not been evaluated or approved by the FDA for safe use in any context, including when added to food. The FDA has received reports of serious adverse events experienced by people who have consumed these products, such as hallucinations, vomiting, tremor, anxiety, dizziness, confusion, and loss of consciousness. The FDA is also concerned that companies are producing delta-8 THC in ways that could result in products with harmful contaminants.

"Marketing edible THC products that can be easily mistaken by children for regular foods is reckless and illegal," said Samuel Levine, Director of the FTC's Bureau of Consumer Protection. "Companies must ensure that their products are marketed safely and responsibly, especially when it comes to protecting the well-being of children."

In June 2022, the FDA warned <u>consumers</u> about consumption of food products containing delta-8 THC. As noted in the warning, the agency received over 125 adverse event reports from Jan. 1, 2021, through May 31, 2022, related to children and adults who consumed edible products containing delta-8 THC. Ten of the reports specifically mention the edible product to be a copycat of popular snack foods.

If a consumer thinks that a product might have caused a reaction or an illness, they should immediately stop using the product and contact their health care provider. The FDA also encourages health care providers and consumers to report adverse reactions associated with FDA-regulated products to the agency using MedWatch or the Safety Reporting Portal.

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Additional Resources:

FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products

- 5 Things to Know about Delta-8 Tetrahydrocannabinol Delta-8 THC
- FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC
- FDA Warns Companies for Illegally Selling Food and Beverage Products that Contain CBD
- FDA Warns Companies Illegally Selling CBD Products
- FDA Regulation of 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.