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FDA, FTC warn of risks to children from copycat food products containing delta-8 THC

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The Food and Drug Administration (FDA) and Federal Trade Commission (FTC) continue to take action against companies illegally selling copycat food products that contain delta-8 tetrahydrocannabinol (THC), an intoxicating substance found in low amounts in the cannabis plant and likely produced by synthetic methods.

The FDA has not approved delta-8 THC products for safe use in any context, and it is illegal under federal law to sell food to which delta-8 THC has been added.

The FDA is particularly concerned that some products containing delta-8 THC are in forms such as candy, chips, cereals and other foods that appeal to children. Furthermore, the product packaging sometimes mimics well-known snack food brands by using similar names, logos or pictures. Children might not be able to differentiate these products from familiar food products.

"We will keep working to protect children from dangerous THC products that look like popular snacks and candies. We all must stay vigilant about these products to keep children safe," said FDA Principal Deputy Commissioner Namandjé Bumpus, Ph.D.



As of August 2024, the FDA and FTC had issued warning letters to 11 companies selling illegal copycat food products containing delta-8 THC, and the FDA independently issued a warning letter to one additional company. The companies no longer offer copycat products for sale on their websites.

What is delta-8 THC?

The *Cannabis sativa* L. plant contains over 500 chemical compounds, more than 100 of which have been characterized as cannabinoids. The most well-known and best-researched cannabinoids are delta-9 THC and cannabidiol (CBD). In general, delta-9 THC is the substance primarily responsible for the "high" associated with use of cannabis products such as marijuana. CBD alone does not cause a high.

Under the Controlled Substances Act, cannabis that contains very low concentrations of delta-9 THC (not more than 0.3% on a dry weight basis) is classified as hemp. Cannabis with higher concentrations of delta-9 THC is defined as marijuana.

Delta-8 THC is a component of cannabis with similar intoxicating effects as delta-9 THC. Delta-8 THC can be found in very small quantities in the cannabis plant, but commercially available delta-8 THC likely is made synthetically from hemp-derived CBD or other source material.

Despite the federally controlled status of marijuana, cannabis products have proliferated in recent years. They are accessible to the public through numerous avenues, including state-regulated dispensaries, as well as retailers such as convenience stores and gas stations selling hemp products. Products containing delta-8 THC sometimes are labeled only as "hemp products," which may cause them to be confused with non- intoxicating hemp products such as CBD.

Concerns related to delta-8 THC and children

Accidental delta-8 THC exposure in children is becoming increasingly common. From Jan. 1, 2021, to Dec. 31, 2023, the FDA received over 300 reports describing adverse events in children and adults who consumed delta-8 THC products. Adverse events included, but were not limited to, hallucinations, vomiting, tremor, anxiety, dizziness, confusion and loss of consciousness.

Nearly half of the reports involved hospitalization or emergency department visits, and approximately two-thirds described adverse events that occurred after ingestion of delta-8 THC-containing food products such as candy or brownies.

In addition, U.S. Poison Control Centers received 2,362 exposure cases of delta-8 THC products from Jan. 1, 2021, to Feb. 28, 2022. About 41% of the cases involved pediatric patients, according to America's Poison Centers National Poison Data System. Forty percent of cases involved an unintentional exposure, 82% of which affected pediatric patients. One case involving a pediatric patient reported a medical outcome of death; however, a causal relationship between delta-8 THC and the events has not been established.

Many cases required evaluation at a health care facility, including admission to critical care.

Guidance for pediatricians

The FDA encourages pediatric health care providers to counsel families about the dangers of cannabis edibles, including those containing delta-8 THC, and accidental ingestion by children.

No antidotes or reversal agents have been approved for THC intoxication.

Health care professionals also are encouraged to report cases of accidental exposure and adverse events to the FDA's MedWatch Safety Information and Adverse Event Reporting Program at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm.

The FDA's Office of Pediatric Therapeutics, Center for Food Safety and Applied Nutrition, and Center for Drug Evaluation and Research contributed to this article.

Resources

- Information from the FDA on delta-8 THC
- Information from the FDA on cannabis research and drug approval process

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