Caught in FDA's Crosshairs: Delta-8 THC Products Invite Increased Scrutiny

Written by Bryant Godfrey, Tina Papagiannopoulos

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The Food and Drug Administration (FDA) issued a consumer alert related to Delta-8 tetrahydrocannabinol (Delta-8 THC), following a recent increase in adverse event reports to FDA and poison control centers. Although Delta-8 THC products have proliferated in the market, FDA has not approved or evaluated any products containing the psychoactive cannabinoid and FDA is concerned that these products are being marketed in a manner that puts the public health at risk.

The 2018 Farm Bill removed hemp, which is defined as cannabis and derivatives of cannabis with no more than 0.3 percent Delta-9 THC from the definition of marijuana in the Controlled Substances Act (CSA). Because the Farm Bill makes no mention of Delta-8 THC, the substance is arguably not regulated as a controlled substance at the federal level but several states have prohibited the sale of Delta-8 because of safety concerns [1].

According to the alert, FDA received adverse event reports from December 2020 to July 2021 concerning 22 patients who consumed the substance and experienced adverse events such as hallucinations, vomiting, trouble standing, and loss of consciousness. National poison control centers received 660 exposure cases in a similar time period, 39% of which involved patients less than 18 years of age. Animal poison control centers have also reported an increase in exposure of pets to these products. As a result, FDA's consumer alert warns consumers to keep these products out of the reach of children and pets.

In addition to the adverse events, FDA is concerned that the products are being marketed with a variety of unproven therapeutic claims, which FDA believes puts the public safety at risk because consumers may use these unproven therapies instead of approved treatments to treat serious diseases. Delta-8 THC has been added as an ingredient in a variety of food products such as brownies, cookies, gummies, chocolates, and other candies, and many of these products are packaged and labeled in a manner that may appeal to children. As we explained in a recent post about cannabidiol (CBD) products, FDA regularly takes enforcement action against food products that are marketed with claims that they can prevent, diagnose, mitigate, treat or cure various diseases or products or that are intended to affect the structure or function of the body under the theory that such products violate the Federal Food, Drug, and Cosmetics Act (FDCA) because they are unapproved new drugs. Unsubstantiated therapeutic claims can also render a Delta-8 THC product misbranded under the FDCA, and foods that contain Delta-8 THC also potentially face enforcement as being adulterated products under the FDCA.

FDA also points out in the alert that some of these Delta-8 THC products are simply labeled as "hemp products" which "may mislead consumers who associate 'hemp' with 'non-psychoactive.'" Delta-8 THC is found naturally in the cannabis plant but in insignificant amounts. Products containing Delta-8 THC in concentrated amounts are typically manufactured from hemp-derived CBD, potentially exposing consumers to much higher levels of the substance than the levels that are naturally occurring in hemp cannabis raw extracts. These products may also contain contaminants because potentially harmful chemicals are often used during the manufacturing process to achieve higher concentration of Delta-8 THC.

On the same day that FDA issued its alert, the Centers for Disease Control (CDC) also issued a health advisory regarding the growing availability of products containing Delta-8 THC. The CDC advisory also discusses the rise in adverse events associated with these products and includes details regarding severe adverse events experienced by two children who ingested a parent's Delta-8 THC-infused gummies as well as adverse events experienced by two adults who mistook the Delta-8 THC products for CBD-like products. The advisory explains that symptoms of Delta-8 THC intoxication are similar to those of Delta- 9 THC intoxication and can include lethargy, slurred speech, uncoordinated movements, increased heart rate progressing to slowed heart rate, low blood pressure, difficulty breathing,

sedation, and coma. According to the CDC, "The rise in delta-8 THC products in marijuana and hemp marketplaces has increased the availability of psychoactive cannabis products, even in states, territories, and tribal nations where non-medical adult cannabis use is not permitted under law."

Following these coordinated safety communications, we can expect to see increased enforcement against products containing Delta-8 THC, particularly products that are marketed in a manner that appeals to children. FDA's recent actions with respect to electronic nicotine delivery system (ENDS) products demonstrate that protecting children from potentially unsafe products is an enforcement priority for FDA. In January 2020, FDA issued an enforcement policy intended to "dramatically limit" children's access to certain flavored e-cigarette products in an attempt to stem the rise in youth e-cigarette use. In August 2021, FDA denied marketing authorization to applications for approximately 55,000 flavored ENDS products from three applicants because they were unable to demonstrate that the benefit to adult smokers was "sufficient to overcome the public health threat posed by the well-documented, alarming levels of youth use of such products."

In addition to facing potential enforcement by FDA, companies that market Delta-8 THC products with unsubstantiated health claims or that misrepresent the nature of their products can face enforcement by the Federal Trade Commission (FTC) for unfair and deceptive practices as well as false advertising. So, despite the possible loophole in the Farm Bill, the federal government can deploy a number of authorities to protect the public against unsafe and unlawfully marketed Delta-8 THC products.

Interested in learning more about Delta-8 THC? We cover it extensively in this blog post on our *Cannabis & the Law* blog.

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[1] Specifically excluded from the definition of tetrahydrocannabinols, a Schedule I hallucinogenic substance in and of itself, is any material, compound, mixture, or preparation that falls within the definition of hemp set forth at 7 U.S.C. §1639(o). See 21 C.F.R. §1308.11(d)(31)(ii).

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