

FDA and CDC Issue Warnings on Potential Dangers of Delta-8 Products

On September 14, 2021, both the CDC and FDA issued warnings related to delta-8 THC (more formally known as Delta-8 Tetrahydrocannabinol) products derived from hemp and the potential for adverse events in persons that have consumed products containing delta-8.

Hemp products are legal under federal laws if they contain no more than 0.3 percent delta-9 THC. The exact definition of hemp pursuant to the 2018 Farm Bill, "... means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts and salts isomers, whether growing or not, with delta-9- tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." There are no specific rules governing delta-8. Delta-8 occurs naturally in hemp, but in small amount; however, delta-8 can be created using CBD isolate from legal hemp. Delta-8 is an isomer, therefore, it currently falls into the definition of hemp under the 2018 Farm Bill. The hemp industry has been utilizing this definition to bring to the market a number of products containing delta-8. These products are becoming more and more common in the hemp marketplace. FDA and CDC are warning that delta-8, like its regulated delta-9 cannabinoid sibling, can also have psychoactive effects. The agencies, based on recent instances of adverse effects in both adults and children who have ingested products containing delta-8 are concerned that consumers, who believe they are taking non-psychoactive hemp products, are in fact being misled by incomplete or misleading labels on delta-8 products.

In the words of the CDC's warning:

As such, products that contain delta-8 THC but are labeled with only delta-9 THC content rather than with total THC content likely underestimate the psychoactive potential of these products for consumers. In addition, the sale of delta-8 THC products is not limited to regulated marijuana dispensaries in states, territories, or tribal nations where marketplaces operate under law. Rather, delta-8 THC products are sold by a wide range of businesses that sell hemp. As a result, delta-8 THC products may also have the potential to be confused with hemp or CBD products that are not intoxicating. Consumers who use these products may therefore experience unexpected or increased THC intoxication.

Both CDC and FDA expressed further concerns that the process of synthesizing delta 8 from CBD could lead to product contamination.

Fortunately for manufacturers and retail sellers of delta-8 products, neither agency proposed any bans on production or sale. That said, those engaged in the business of manufacturing and/ or selling delta-8 products should focus their attention on appropriate labeling and testing, in line with any requirements in states in which they do business. Several states, including Florida, Indiana, and Utah already require QR codes on product labels that direct consumers to third party testing results. It should be anticipated that more states will follow and begin to regulate delta-8 products.

FisherBroyles

Client Alert

September 16, 2021 | Page 2 of 3

Many states and plaintiff's personal injury lawyers are purchasing delta-8 products and testing the products to determine if the delta-8 product has over the 0.3 delta-9 limit for a hemp product. The state agencies and lawyers are starting investigations or sending cease and desist letters to manufacturers and many of these manufacturers are learning they have purchased delta-8 from an extractor with a certificate of analysis, only to learn that laboratory report was intentionally not reporting delta-9.

Regardless of current regulatory schemes, or the lack thereof, manufacturers and sellers of delta-8 products should consider "getting ahead of the game" and move to:

- Secure third party, independent testing of all delta-8 products, and obtain certificates of analysis (COA) that validate product content.
- Provide proper labeling, whether through QR codes or other mechanisms that provides clear and transparent information to consumers regarding product content.

For those interested in a more in-depth discussion of delta-8 in the marketplace, attorney Brian Dickerson recently participated in a town hall discussion sponsored by the Florida Department of Agriculture and Consumer Services. The video is available on YouTube at <https://youtu.be/7QKMz2Q8hek>.

The FisherBroyles Pharmacy and Health Care Law team is pleased to keep you updated on events of interest to those in the healthcare, medical device, and pharmaceutical industries. Questions related to the subject matter of this alert may be directed to any of following attorneys.

Brian E. Dickerson
brian.dickerson@fisherbroyles.com
202.570.0248

Anthony J. Calamunci
Anthony.calamunci@fisherbroyles.com
419.376.1776

About FisherBroyles, LLP

Founded in 2002, FisherBroyles, LLP is the first and world's largest distributed law firm partnership. The Next Generation Law Firm® has grown to hundreds of partners practicing in 23 markets globally. The FisherBroyles' efficient and cost-effective Law Firm 2.0® model leverages talent and technology instead of unnecessary overhead that does not add value to our clients, all without sacrificing BigLaw quality. Visit our website at www.fisherbroyles.com to learn more about our firm's unique approach and how we can best meet your legal needs.

These materials have been prepared for informational purposes only, are not legal advice, and under rules applicable to the professional conduct of attorneys in various jurisdictions may be considered advertising materials. This information is not intended to create an attorney-client or similar relationship. Whether you need legal services and which lawyer you select are important decisions that should not be based on these materials alone.

© 2021 FisherBroyles LLP