

The Federal Government & CBD – What the FDA is Happening?

Cannabis Business Legal News

By Darren Grady on January 26, 2023

Many of us following the ever expanding cannabis industry in the United States have seen more and more CBD-infused food and drink products hitting the market and becoming readily available for consumers. There are CBD gummies, cookies, elixirs, seltzers, sodas, coffees, smoothies, and anything else you might imagine. These products are available all over the place, from high end grocery stores to bodegas, and everywhere in between. What people may not know, however, is that **CBD-infused products remain illegal at the federal level.** CBD, short for cannabidiol, is a compound in cannabis which has recognized medical value, but does not produce the high or euphoria created by the more commonly known cannabis compound THC. The United States legalized CBD derived from hemp in December of 2018.

In 2018, the FDA approved Epidiolex, the very first CBD medication cleared for patient use in the United States. Somewhat ironically, this approval once gave the FDA pause in its formal position on CBD in food and drink products. The FDA's official position has clearly been that CBD-infused food and drinks were illegal because none of those products had gone through the rigorous regulatory testing to which Epidiolex was subjected before approval. In the spring of 2019, the FDA indicated a possible position change, when the then outgoing FDA chief Scott Gottlieb spoke about the potential for legalizing CBD infused food and drinks as long as those products met certain regulatory standards.

The FDA's formal statement included the following: "There are open questions about whether some threshold level of CBD could be allowed in foods without undermining the drug approval process or diminishing commercial incentives for further clinical study of the relevant drug substance." In late 2018, the FDA released a statement saying that it would crack down on CBD in food and drinks (and there were inspections, penalties, and fines on certain retailers nationwide, notably in New York, Ohio, California, and Maine). At the very least, Chief Gottlieb's statements in 2019 indicated that the FDA was envisioning a world where certain CBD-infused food and drinks could be legal at the federal level.

So what has happened since then? Well, the CBD market has continued to grow at an incredible rate. According to Forbes, one forecast predicts that the market will climb to \$19.5 billion by 2025. This projection includes a compound annual

growth rate of nearly 37%. There is, however, a catch (and it's a BIG catch): The estimate hinges on whether the FDA will finally approve CBD as a legal additive to consumer products. Despite the seemingly positive movement in 2018-2019, the FDA is maintaining a very cautious and measured approach with CBD, and CBD infused food and drinks remain illegal and subject to great scrutiny.

In an article posted by the FDA in late 2022, the agency explained that "the data on CBD point to real risks that need to be considered. Risks include liver injury, harm to the male reproductive system, and side effects, such as changes in alertness and other symptoms. In addition, drug interactions -- taking CBD with other medications -- may increase or decrease the effects of other medications, which may lead to more side effects from, or decreased effectiveness of, the other medications."

In that same article, the FDA acknowledged that there is great public interest in CBD, despite the fact that CBD cannot lawfully be added to foods or dietary supplements. Further, the FDA stated that it is continuing to explore "policy solutions to address the large, violative market of CBD products" and that it would continue to monitor the CBD market and would take action, as needed, against companies that it feels pose a high risk of harm to the public. In November of 2022, the FDA issued warning letters to companies for illegally selling foods with CBD (and Delta-8 THC), including products that the FDA felt appealed to children.

In short, there has not been any real CBD policy movement by the FDA in the past couple of years. It is certainly possible that the FDA's focus on COVID-19 and addressing vaccines may have prevented the agency from addressing other issues, including CBD. US legislators have certainly noticed the delay. Rep. James Comer, the chair of the US House Oversight Committee, commented recently that the committee desires to question the current FDA Commissioner Robert Califf regarding the agency's lack of movement on a number of issues, including CBD. It remains to be determined when this committee questioning will occur.

Currently, CBD businesses wishing to infuse the compound into food and drinks must take on a certain amount of risk and bet on the eventual legalization of CBD infusions. While the FDA certainly still seems very cautious and hesitant about legalizing these products for the time being, it is also likely that CBD infusions will eventually become legal in some form (but highly-regulated). Manufacturers, marketers, distributors, and retailers of CBD-infused food and drinks, and those wishing to enter this exploding market, should certainly keep an eye on the FDA's position and comments in 2023. In the past, the FDA has held public hearings on CBD and has taken comments from the public. The FDA continues to gather data on the safety of CBD in food products as well as feedback on how the FDA could regulate certain aspects of the industry (including manufacturing, marketing, and labeling). Additionally, the FDA openly encourages individuals to submit comments, data, and information related to

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cannabis and cannabis-derived products, including CBD, to the public docket, which the FDA reopened in March of 2020. FDA reopened the docket to provide a public and transparent way for those in the industry to provide new and emerging information to the FDA in real time. In 2023, for those in the industry, it is important to make your voices heard by posting comments and information for the FDA to consider as it continues to grapple with its position and policy on CBD.

Update: Things happen fast in this space. Today, January 26th, the FDA released a statement concluding that the current regulatory framework for food and supplements are simply not appropriate for CBD! Looks like this is up to the lawmakers in congress now!

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