Updates
May 31, 2019

Food and Drug Administration Considers Pathway for Legalizing CBD at Public Hearing

On May 31, 2019, the Food and Drug Administration (FDA) held its first public hearing concerning products containing cannabis or cannabis-derived compounds (in particular, cannabidiol (CBD), a popular additive to food, beverages and supplements). This new focus reflects the burgeoning popularity of CBD as an additive to consumables, driven largely by the compound's much-touted health benefits. For example, *Forbes* reported that "[e]stimated retail sales of CBD consumer products in 2018 … ranged between $600 million and $2 billion" and quoted a recent study estimating the CBD market at $16 billion by 2025.

The key takeaways from the hearing are as follows:

- Market demand for CBD products is significant and growing (roughly one-in-four adults have used CBD products), and consumers are using CBD products for a broad variety of health, wellness, and food and beverage purposes.
- There is a clear need for immediate guidelines regarding appropriate labeling, usage and research.
- There is also a strong need to research dosage, safety and adverse effects, and appropriate usage with respect to intended effects.
- The FDA is concerned about CBD products' purity (i.e., the presence of pesticides, heavy metals, other contaminants or unlisted compounds).
- There is a need to ensure that CBD products contain legal quantities of THC and accurately state the amount of CBD present.
- The FDA is particularly concerned by exaggerated and overreaching health claims in CBD marketing.
- The FDA committed itself to taking a science-based approach to establishing sensible regulations for CBD products, but—unfortunately—has no timeline for achieving this goal.

The FDA, acknowledging its inconsistent treatment of CBD to date, sought information at the hearing in order to adapt its regulatory strategy, and to clarify and streamline pathways to legally market CBD-infused products.

Questions Remain Regarding CBD's Legal Status and Properties

Despite the explosion in CBD activity, its legal status is unresolved. CBD is a non-psychoactive compound present in the cannabis plant that can be derived from either hemp or marijuana. It can be administered as CBD oil or added to foods, beverages and oral supplements. CBD derived from hemp is no longer an illegal controlled substance at the federal level under the 2018 Farm Bill (which removed industrial hemp, defined as cannabis that contains less than 0.3% THC dry-weight, from Schedule I of the Controlled Substances Act), and in 41 states plus the District of Columbia. On the other hand, CBD derived from marijuana, which is legal recreationally in 10 states and the District of Columbia, and medically in 23 additional states, remains subject to federal criminal prosecution.

As noted above, CBDs' purported health benefits are unproven. That, however, has not stopped some companies from making extravagant claims about CBD-infused products, prompting regulatory concern by the FDA.

Although FDA Deems CBD "Unsafe," There Has Been No FDA Enforcement

The FDA currently classifies all products containing CBD (including those derived from hemp, in accordance with the 2018 Farm Bill) as "unsafe" under the federal Food, Drug and Cosmetic Act. Despite this designation, the agency's general approach to CBD enforcement suggests that CBD has gained widespread acceptance and that it does not believe the substance should face outright prohibition.

Under the Food, Drug and Cosmetic Act, a substance must be generally recognized as safe by relevant experts, which has not happened yet with respect to CBD. Consequently, the FDA has not approved CBD as an additive. Nevertheless, CBD-infused food and beverage products continue to multiply in the marketplace, and the FDA has taken no action to remove such products from the shelves. The CBD, food, beverage and supplements industries have been demanding clarity, especially because hemp-derived CBD products are legal at the federal level; so, too, has the U.S. Congress.

Unfortunately, the FDA's policy regarding CBD marketing claims is murky: while the agency has policed companies making unapproved therapeutic claims, which the FDA states are illegal, the agency has not taken any enforcement action to date. From 2015 to date, the FDA sent a mere 22 warning letters to companies for deceptive marketing regarding the therapeutic qualities of CBD (e.g., "contains CBD oil to alleviate anxiety"). But this activity has been toothless. The warning letters targeted only egregious offenders that made putatively extreme and unsupported specific claims regarding the health benefits of CBD, and the FDA has not initiated *any* enforcement actions against *any* company marketing CBD-infused products.

Acknowledging this ambivalence regarding CBD policy, the FDA scheduled Friday's hearing to gather the information it needs to work out a coherent, informed and comprehensive approach to the substance. Outgoing Commissioner Scott Gottlieb explained that the hearing would "give stakeholders an opportunity to provide the FDA with additional input relevant to the agency's regulatory strategy related to existing products, as well as the lawful pathways by which appropriate products containing cannabis or cannabis-derived compounds can be marketed, and how we can make these legal pathways more predictable and efficient."

What We Learned at the Hearing

The FDA's Acting Commissioner, Dr. Norman Sharpless, opened the meeting with brief, but illuminating, remarks. Dr. Sharpless acknowledged the great interest in CBD products, but also noted that CBD raised important healthcare concerns requiring further research and clarity, including safe dosages, drug interactions and tolerance among populations such as children, the elderly and pregnant women. The core challenge of regulating CBD, he explained, arises because the FDA's regulatory apparatus was designed to treat drugs and food/beverage additives separately. Thus, the FDA needs to consider thoughtfully how to regulate this substance, which is already being used widely in both categories. He also emphasized that marketing claims regarding CBD health benefits are an ongoing concern for the FDA, especially unproven claims, such as its ability to treat serious diseases, including cancer. Dr. Sharpless ended by stating that the FDA is focused on taking a science-based approach to resolving this concern, and to that end, the agency has established an internal working group.

Following these comments, a panel of agency officials received concise briefings from speakers representing primarily the academic, agricultural, manufacturing, health, retail and distribution, and public safety communities. Several consistent themes emerged from these diverse perspectives.

The FDA is lagging behind the marketplace. There is a surging demand in the marketplace for CBD products. Commenters consistently acknowledged regulatory guidelines' importance in keeping the industry on track and noted that such guidelines will also help focus research efforts (which are necessary to protect consumers), ensure responsible labelling and help the industry understand where risks and priorities are. Lack of regulation, commenters clearly indicated, is creating a proverbial "Wild West," in which consumers cannot trust that products are accurately labeled, pure and safe. Market participants, as well, are hampered by lack of clarity as to what they can and cannot do. Several commenters suggested that the market cannot afford to wait through an extended, years-long rulemaking process.

Health benefits, but also concerns. Most commenters agreed that available data and anecdotal evidence pointed to health benefits, especially as to specific afflictions, such as anxiety, insomnia, pain management and epilepsy. Commenters generally agreed, however, that additional product testing and clinical research into efficacy, adverse effects and drug interactions was necessary. A small minority expressed skepticism or caution. The FDA's questions indicated that there is strong interest on the agency's side, as well, in obtaining substantive additional data on these questions.

There is clinical data, but more research is called for. Some commenters pointed to a new and slowly growing body of clinical data, but almost all commenters agreed that additional research is necessary for clarity both for the FDA to properly regulate, and for consumers to make safe, informed choices.

Labelling integrity is a particular challenge. Academics and health professionals, in particular, cited the need for clear standards regarding how CBD products are labelled. For example, CBD products may contain undesirable substances, such as synthetic cannabinoids, or high levels of THC. Without enforceable guidelines, there is a great potential for misleading consumers and health patients. (For example, commenters indicated, a large percentage of CBD extract is under-labelled, over-labelled or mislabeled.)

CBD purity remains a challenge. Many commenters expressed concern that existing studies reflected the presence of heavy metals, pesticides and pollutants, and bacteria in CBD products, a result of the products' current unregulated status.

Speakers consistently welcomed the rigor of FDA scrutiny. Commenters agreed that FDA attention and regulation would establish guiderails necessary to make the CBD market safer, more understandable to consumers and more consistent—all qualities that will fuel, not hinder, continued growth.

Next Steps

For companies that seek to do business in the exploding CBD market, the FDA hearing raises a number of important issues.

First, manufactures, distributors and retailers should approach the product responsibly. Marketing and labelling should be scrupulously accurate, and we continue to recommend strongly against making extreme or unsupported health claims (the FDA's history of warning letters provides a useful practical delineation for what is unacceptable).

Second, it is clear that the FDA, as an institution, understands the widespread acceptance of CBD (among other cannabis-related products), and presumably the need for oversight in order to provide useful guardrails for businesses, consumers and researchers alike.

Third, unfortunately, those guardrails may not be available for some time. The FDA appears to be working towards generating thoughtful guidelines regarding CBD and cannabis-related food, beverages, drugs and supplements, but the agency has not publicly set any deadlines for itself in this regard. Given the time-consuming process generally required by federal government rule-making, it may take a while for the FDA to generate regulations to help promote clarity in the CBD marketplace.

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