

# FDA Requests Data and Information at Public Hearing on Products Containing Cannabis or Cannabis-Derived Compounds

June 6, 2019

Food, Drugs, and Devices

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Last Friday (May 31, 2019), FDA hosted a public hearing on “[Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds](#).” The hearing followed FDA’s [notice in the Federal Register](#) on April 3, 2019, announcing the public hearing and establishing a public docket to obtain information related to cannabis and cannabis-derived compounds. The hearing was FDA’s first public event dedicated to regulation of cannabis-derived compounds.

Representatives from FDA’s Commissioner’s Office, Office of Chief Counsel, Center for Food Safety and Applied Nutrition (CFSAN), Center for Drug Evaluation and Research (CDER), and the Center for Veterinary Medicine (CVM), among others, participated in a [panel](#) overseeing the hearing. Acting FDA Commissioner Ned Sharpless opened the hearing by describing FDA’s authorities and the current environment related to regulation of products containing cannabis or cannabis-derived compounds. Afterwards, pre-selected stakeholders presented oral comments and formal remarks to the FDA panel.

Most presenters at the meeting urged FDA to take some level of regulatory action related to cannabis and cannabis-derived compounds, noting confusion and uncertainty regarding the regulatory status and safety of cannabis-derived compounds. FDA often asked presenters questions at the end of their allotted time; the scope of questions indicated that FDA is grappling with a number of unresolved issues. This alert provides a summary of these issues below.

Stakeholders may submit comments and data to FDA’s [public docket](#) through July 2, 2019. Submissions to docket, as well as information provided at the public hearing, will help shape the direction of the Agency’s regulation of products with cannabis-derived compounds.

## Safety of Cannabis-Derived Products

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Acting FDA Commissioner Sharpless set the tone for the hearing by focusing many of his opening remarks on the safety of cannabis-derived products, particularly CBD. Sharpless asked, among other questions, “[H]ow much CBD is safe to consume in a day? What if someone applies a topical CBD lotion, consumes a CBD beverage or candy, and also consumes some CBD oil? How much is too much? How will it interact with other drugs the person might be taking? What if she’s pregnant? What if children access CBD products like

gummy edibles? What happens when someone chronically uses CBD for prolonged periods?” FDA asked for data around these questions throughout the day.

In particular, FDA questioned many presenters and requested additional data on the following topics:

- **Cumulative exposure.** FDA asked presenters about how to evaluate and account for cumulative exposure of cannabinoids across many products. FDA was particularly interested in data, including data from international markets, around consumption of cannabis-derived products.
- **Adverse events.** FDA asked presenters to provide information on serious and non-serious side effects associated with hemp and CBD use. FDA asked many presenters to provide systematic data on adverse events associated with commercially-available hemp or CBD products.
- **Drug interactions.** Presenters provided information on the potential for interactions between various categories of cannabis-derived products, particularly CBD and drugs, and FDA specifically requested more data on the potential for such interactions.
- **Safe and unsafe dosing levels.** FDA was interested in how manufacturers determined dosing for their products and what amount is treated as safe or unsafe (e.g. NOAEL and LOAEL levels, maximum daily exposure levels) in both foods and supplements, recommended serving sizes, and how those recommendations would change based on the product’s effects. FDA asked presenters to submit data to underpin their decisions about dosing in their products.
- **Hepatotoxicity or other toxicity.** FDA wanted to understand whether CBD and hemp extract could result in toxicity, particularly what levels could result in liver toxicity.
- **Effects on vulnerable populations (e.g. children and geriatrics).** FDA was interested in data supporting the safety of hemp extract or CBD use in vulnerable populations, particularly children. FDA asked several retailers whether they sell CBD products to children and how retailers decided on an age cut-off, such as 21, for CBD products.

FDA asked stakeholders to submit any studies or data on the topics above to the public docket. Following the meeting, Dr. Amy Abernethy, Principal Deputy Commissioner, tweeted, “[k]ey questions about product safety need to be addressed. Data are needed to determine safety thresholds for CBD.”

## Undefined Terms Describing Products Containing Cannabis-Derived Compounds

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FDA wanted definitions of common terms used to describe commercially available cannabis products and asked presenters for a list of terms in the cannabis industry that could benefit from standardization.

Commercially available cannabis products are marketed with many industry-specific terms without formal definitions. Some of these terms describe the product itself. During the meeting, many speakers referenced “hemp extract,” which often refers to cannabis-derived extract consisting of the cannabinoids and other substances naturally present in hemp. “Hemp extract” could be “full spectrum hemp extract,” which typically contains all of the cannabinoids present in

hemp, or “broad spectrum hemp extract,” which typically contains cannabinoids and other substances found in cannabis, but excludes THC. “CBD isolate” typically describes CBD without the other components found in hemp. Presenters acknowledged a lack of clear standards around these terms.

Speakers during the meeting also acknowledged a lack of consensus on terms used to characterize ingredients in cannabis products. Entities use “THC-free” on product labels, but it is unclear whether the term means that the product is wholly devoid of THC or whether it contains some minimally-detectable amount of THC. One speaker suggested that more guidance would be helpful around how much THC can be in a concentrated or manufactured product when the Agricultural Marketing Act defines hemp to mean cannabis with not more than 0.3% THC on a dry weight basis.

## **Characterization of Hemp Extract and Naturally-Occurring CBD**

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FDA was interested in how to characterize hemp extract and how to determine what levels of CBD may be naturally-occurring in hemp. In response to presenters who argued naturally-occurring CBD in hemp should not be excluded in foods and dietary supplements, FDA asked stakeholders to clarify what they meant by “naturally-occurring levels.” For example, FDA asked about what CBD levels would one expect to naturally occur in a cannabis plant. FDA also asked whether CBD would be naturally-occurring if extracted from cannabis strains specifically cultivated for high levels of CBD. FDA then asked whether CBD would be naturally-occurring if extracted from only certain parts of the hemp plant, known to have higher levels of CBD. Presenters struggled to quantify such levels in response to FDA’s questions, noting that levels would vary based on the strain, extraction process, and plant part.

Along the same lines, FDA was interested in the processes used for extracting cannabis-derived products, particularly hemp extract. FDA asked multiple presenters about their manufacturing process for creating hemp extract. In one exchange, FDA asked a manufacturer whether it removes certain components during the extraction process and whether the extract undergoes some type of processing to concentrate certain compounds. FDA was also interested in what happens to the waste stream during the extraction process.

## **Commercial Availability of Cannabis-Derived Products and Incentives for Drug Development**

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FDA has taken the position that CBD may not be used as an ingredient in foods and dietary supplements because of the exclusionary clauses in sections 301(ll) and 201(ff)(3)(B) of the Federal Food, Drug, and Cosmetic Act (FDCA). FDA can only override these threshold exclusions through rulemaking. During the meeting, FDA emphasized how unusual such a move would be for the Agency. In his opening remarks, Acting Commissioner Sharpless stated that “[a]lthough the law says that FDA can issue regulations to create new exceptions to these statutory provisions, FDA has never issued a regulation like that for any substance...[and] [t]here are important reasons to generally prohibit putting drugs in the food supply.”

Throughout the hearing, FDA was interested in understanding how commercial availability of cannabis-derived products, particularly CBD, would affect incentives for drug research and development. FDA was particularly interested in how the current availability of cannabis derivatives has incentivized or dis-incentivized companies from developing medicines with

cannabis-derived ingredients. One industry trade group argued that the FDCA's exclusionary clauses were not intended to ensure product safety but to preserve incentives for drug development.

FDA also questioned presenters on current use of commercially-available cannabis derivatives, asking patient groups whether the current availability of cannabis derivatives have led patients to use CBD-containing foods and dietary supplements rather than FDA-approved drugs to treat medical conditions. Some patient groups responded that access to CBD food and dietary supplements would not discourage patients from taking CBD-based drugs. Some advocates argued for the use of CBD in foods and dietary supplements by asserting that such uses would expand access to CBD for individuals who want certain non-drug benefits. Other patient groups responded to FDA's questions by arguing that clinical trial results could be compromised if investigators cannot control dietary intake of cannabinoids and urged FDA to prohibit cannabis-based additives in FDA-regulated products. *Consumer Reports* presented the results of a survey indicating that a significant proportion of individuals using CBD had stopped taking OTC drugs or opioids as a result.

## **Functional Use of Hemp Extract and CBD in FDA-Regulated Products**

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Throughout the meeting, certain stakeholders supported using CBD and hemp extract in cosmetics, foods, and dietary supplements, although the specifics of an ideal federal framework varied. FDA asked for information around the functional use of CBD in cosmetics and foods. FDA also asked one speaker if the speaker had data on the functional purpose of CBD in a cosmetic. FDA was interested in evidence of CBD's cosmetic effects and data on transdermal absorption. Likewise, FDA wanted to understand the functional effect of CBD in food. FDA asked one speaker whether the speaker had seen evidence of CBD's use in food for its taste, aroma, or nutritive value.

FDA also asked presenters to clarify the status of hemp, CBD, and other cannabis-derived products intended for use in animals. In an exchange with FDA, the Association of American Feed Control Officials (AAFCO) informed FDA that states do not recognize the legality of hemp-derived products in animal feed but that state officials are seeing CBD in such products, especially pet food. Some state agencies, such as the Pennsylvania Department of Agriculture, are issuing stop-sale orders for CBD in pet food. AAFCO also informed FDA that it had not yet seen CBD in feed for food-producing animals (but had seen CBD being used in feed for horses), and that CBD products are generally being found in the pet treats and dietary supplements.

## **Synthetic CBD vs. Natural CBD**

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FDA was interested in understanding the market for synthetic CBD. FDA also asked presenters whether they had any data on the safety of synthetic CBD and whether presenters were aware of any risks related to synthesizing CBD compared to CBD derived from cannabis.

## **Standards for Manufacturing and Labeling Cannabis-Derived Products**

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Some stakeholders asserted that FDA should leverage its long experience in regulating foods, beverages, and dietary supplements and apply the same regulatory standards to cannabis-

derived compounds in such products. One presenter articulated that bad actors are exploiting the current situation to make unsubstantiated claims and derive CBD and other compounds in a manner not in compliance with CGMPs. The low barrier to entry for non-drug products leads to cannabis-derived products with varying levels of THC, chemicals, and other cannabinoids. Many advocated for compliance with CGMPs using third party verification as a way to help ensure the quality of such products. FDA asked presenters how many cannabis manufacturers currently complied with relevant CGMPs and whether the presenters believed most manufacturers were complying with CGMPs.

Many presenters expressed concern about claims made about currently commercially-available cannabis products. Academics pointed to studies finding that many commercially-available cannabis products were misbranded. They reported that some products did not contain the CBD in quantities claimed on the label. They also reported products labeled as “THC-free” that in fact contain over 40% THC. The Agency invited stakeholders’ viewpoints on labeling requirements for cannabis and cannabis-derived products.

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Interested stakeholders should consider submitting written comments to the docket providing data and information responsive to FDA’s questions and the key areas of interest summarized above; the current deadline for comments is July 2, 2019. Covington will continue to monitor FDA’s activities in this space and share any key regulatory developments.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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