FDA Elaborates on its Hopes for Collaborating with Congress on a CBD "Harm Reduction Approach" During Stakeholder Call

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PRACTICES CBD and Hemp, FDA Regulatory and Compliance

On May 25, 2023, FDA held a virtual Stakeholder Call regarding the agency's plans for "A New Way Forward for Cannabidiol and Other Hemp Products."[1] During the call, FDA summarized its plans for partnering with Congress to establish potential regulatory pathways for products containing hemp-derived cannabidiol ("CBD"), summarized some of its remaining concerns and knowledge gaps regarding CBD's safety, and expressed an overarching interest in developing an approach toward CBD that focuses on harm reduction, rather than harm elimination.

Why did FDA hold the CBD Stakeholder Call?

FDA hosted the Stakeholder Call to provide important information to industry, trade associations, and legal and policy organizations about the agency's conclusion that a new regulatory pathway is needed to provide appropriate regulatory oversight for CBD products, and to provide additional clarity on FDA's intent to work with Congress on a new path forward following FDA's initial announcement of such plans in January 2023.[2]

Who spoke on FDA's behalf during the Stakeholder Call?

Dr. Patrick Cournoyer, Senior Science Advisor and Lead for the Cannabis Product Committee, Dr. Janet Woodcock, Principal Deputy Commissioner, and Norman Birenbaum, Senior Public Health Advisor represented FDA during the call and spoke on different topics related to the agency's plans for finding a path forward for CBD.

What were the key takeaways from the Stakeholder Call?

FDA emphasized that existing regulatory pathways for foods and dietary supplements are not appropriate for CBD for multiple reasons, including still-uncertain concerns and questions regarding the safety of CBD. FDA intends to work in tandem with Congress to develop a new pathway for CBD that will focus on reducing harm without impeding stakeholders by creating room for regulatory oversight that will enable consumers to make informed decisions about their health and have trust in what they are buying. The new pathway will take time to develop and will require significant input and direction from Congress. In the meantime, FDA will continue prioritizing enforcement for the CBD products that pose the greatest immediate risks to consumers while it collaborates with Congress on developing a potential new legislative pathway for CBD in the future.

Why does FDA want to work with Congress on developing a new pathway for CBD?

After continuing to evaluate the issue since its January 2023 announcement, FDA has determined that the existing regulatory frameworks at its disposal for foods and dietary supplements are not appropriate for CBD. During the Stakeholder Call, FDA reiterated that its intent regarding potential

CBD rulemaking has historically been clear, and that the agency's position has always been that it would only consider initiating rulemaking for establishing CBD as an ingredient in foods or dietary supplements if FDA could determine that the ingredient meets all applicable requirements under the FD&C Act, including by meeting FDA's standards for safety as a potential food or supplement ingredient. However, after collecting information from industry, monitoring adverse events, and studying other information and data available regarding CBD, FDA still has remaining safety concerns regarding CBD that are not typical for most other food ingredients, and the agency does not intend to initiate rulemaking itself at this time to establish a regulatory pathway for the cannabinoid. Instead, because of CBD's potential risk profile and the agency's existing "highly protective" safety standards for food and supplement ingredients, which don't allow for much, if any, risk, FDA believes that Congress is better equipped to develop a path forward for CBD that *would* allow for some risk, while still incorporating enough regulatory oversight to protect consumers by reducing the potential for harm posed by the ingredient.

What does FDA currently envision for the new pathway?

Although FDA repeatedly emphasized during the Stakeholder Call that the specifics of a new scheme for regulating CBD will ultimately be in Congress's hands, the agency noted that the new framework could include elements aimed at providing a basic level of regulatory oversight to create guardrails for CBD products, without going so far as to create a product-by-product premarket approval process. Overall, FDA envisions a framework that would focus on harm-reduction rather than harm-elimination by incorporating certain features, such as measures aimed at reducing the risk of contaminants in CBD products, CBD content limits, clear labeling requirements, and elements to mitigate the risk of children ingesting CBD. The overall goal of this approach would be to create a framework that helps consumers make informed decisions about their health and seek out responsible actors in the industry so that they can have trust in what they are buying, without providing so much oversight that it impedes stakeholders' efforts entirely.

Why does FDA still have safety concerns about CBD?

There are still significant data gaps regarding the potential risks posed by CBD, some of which are due to the rapid speed with which the market for CBD products has developed since the issuance of the 2018 Farm Bill and the fact that little data still exists regarding the effects of long-term CBD consumption. In particular, because CBD is highly bioactive and commonly used by consumers as a way to self-medicate, its use as a potential ingredient in foods or supplements still raises important safety concerns in FDA's eyes, especially because using food to administer CBD may make it difficult for consumers to know and control how much they ingest. Additionally, some of the available data that FDA has reviewed since it began its CBD fact-finding mission in 2018 suggest the potential for CBD to cause adverse health effects, such as potential harm to the liver, possible drug interactions (including with caffeine), risks of harm to the male reproductive system, and heightened health risks for vulnerable populations like children and pregnant women. Collectively, these risks are largely responsible for FDA's unwillingness to pursue using existing regulatory pathways for food and supplement ingredients as a way forward for regulating CBD on the consumer market. FDA also noted during the Stakeholder Call that it has received many adverse event reports related to products containing delta-8 THC, and that the agency is therefore still concerned about potential risks posed by this second cannabinoid that has rapidly emerged on the market.

Does FDA still plan to take enforcement action with respect to CBD products?

Yes. For now, FDA plans to continue prioritizing enforcement against the CBD products that pose the most immediate risks. Historically, FDA has prioritized for enforcement CBD products that are marketed or advertised with health claims, and for at least the foreseeable future, the agency will likely continue this enforcement approach while seeking to collaborate with Congress on a new legislative pathway for the popular cannabinoid.

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[1] U.S. FOOD AND DRUG ADMIN., Stakeholder Call: A New Way Forward for Cannabidiol and Other Hemp Products (May 25, 2023).

[2] See U.S. FOOD AND DRUG ADMIN., FDA Statement: FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward (Jan. 26, 2023).