Updates
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Outgoing FDA Commissioner Proposes Expedited Steps for Approval of CBD

Following the recent public hearing held by the Food and Drug Administration (FDA) regarding the safety and efficacy of cannabidiol (CBD), many in the food and beverage industry asked how long it will take for the agency to establish a regulatory pathway for approval of CBD as a food additive. As is commonly recognized, establishing this pathway is critical given the significant market for CBD products, which has apparently outstripped the FDA's ability to provide guidance. On July 31, 2019, the FDA's outgoing commissioner, Dr. Scott Gottlieb, publicly proposed an expedited regulatory pathway for legally selling CBD in food and beverage products. If followed, Dr. Gottlieb's proposal would offer critically needed relief to both companies in the CBD business and the consumer that buys CBD products.

The CBD Market Is Exploding, but Questions Remain

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 the agency does not believe the substance should face outright prohibition and that CBD has gained widespread acceptance.

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 overt action to remove such products from the shelves (the FDA has sent warning letters to companies that have made egregious health-related claims, but there have been no enforcement actions). Affected industries and the U.S. Congress have been demanding regulatory clarity.

The FDA's recent hearing revealed a conflict between surging demand for CBD products and current lack of regulation, which is creating a proverbial "Wild West." On the one hand, businesses lack guardrails regarding basic things, such as labelling, while on the other hand, consumers cannot trust that products are reliably advertised, pure and safe. Most commenters agree that available data and anecdotal evidence point to health benefits but also agree that additional product testing and clinical research into efficacy, adverse effects and drug interactions is necessary. Labelling integrity emerged as a particular challenge, with an unsolved 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. Many commenters likewise expressed concern about CBD purity, noting 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.

Petitions for FDA Approval of CBD Products Would Circumvent Lengthy Rulemaking

Dr. Gottlieb's recommendations echo a theme that emerged at the FDA hearing: The CBD market cannot wait through an extended rulemaking process. Notice and comment rulemaking spans years; for example it takes the Occupational Safety and Health Administration (OSHA) within the U.S. Department of Labor an average of 10 years to develop and promulgate a health or safety standard. With the CBD market projected to reach $20 billion by 2020, observers—including Dr. Gottlieb—worry that its rapid growth is overtaking the FDA's ability to regulate through traditional mechanisms.

To facilitate faster regulation of CBD, Dr. Gottlieb proposes that manufacturers petition the FDA for permission to add CBD to specific food and beverage products, which would circumvent the slow-moving notice and comment process but remain unique to CBD products. According to Dr. Gottlieb, such submissions could be in the form of ingredient notifications or food additive petitions (including toxicity studies).

Under this proposal, the FDA would require CBD-infused products to meet criteria addressing outstanding concerns about CBD, as raised in the FDA's hearing. These concerns include "meeting good manufacturing requirements, demonstrating traceability, adhering to safe levels for the purity and potency of the CBD being added, and demonstrating that CBD is being added to food products only in very low concentrations that are unlikely to pose health risks." Labeling concerns could also be addressed through FDA directives specifying that CBD-infused products may not claim to treat diseases and must substantiate with evidence any claims to help with various conditions, such as stress or insomnia. Congress would need to lay a foundation for this process by passing legislation clarifying that the FDA need not issue sweeping regulation of CBD but may "instead rely on petitions filed by individual, prospective producers."

Thus, FDA could approve CBD products significantly more quickly while protecting consumer safety and providing appropriate guidelines for manufacturers to follow without concern that action would be taken against them. The FDA petition process to recognize an ingredient as safe, for example, typically takes around 180 days, rather than years (or decades) needed to promulgate a new rule.

Dr. Gottlieb's Proposal Offers Potential Way Forward and Guidance

Dr. Gottlieb's proposal is helpful in two regards. First, if followed by the FDA, the proposal would enable companies involved in the CBD market to operate confidently inside a consumer-friendly regulatory framework within a period of months. Second, in his proposal, Dr. Gottlieb highlights areas of concern consistent with Perkins Coie's prior advice to businesses offering CBD-infused products. In particular, to reduce the risk of FDA action against CBD products for deceptive marketing practices, manufacturers should use terms such as "maintain," "support" and "promote" to soften promotional claims regarding CBD products (i.e., the product "contains calcium to support strong bones"), avoid claims that products can treat diseases, describe the role in the product of the nutrient or ingredient intended to affect the human body's normal structure or function, and to the extent possible substantiate claims made regarding the product. Likewise, dosage and quality should be scrupulously labeled and substantiated.

In sum, Dr. Gottlieb's thoughts, while not officially connected to the FDA, indicate that there may be a potential expedited path for legalizing CBD in food and beverages. This path is sorely needed given the current popularity of CBD products.

Authors

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