The Not So Weaved Web: The Fate of CBD Products is in FDA's Hands

Written by Bryant Godfrey, Tina Papagiannopoulos

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More than two years have passed since hemp-derived cannabidiol (CBD) was legalized in the United States under the Agriculture Improvement Act of 2018 (also known as the "Farm Bill"). The Food and Drug Administration (FDA) has been exploring potential regulatory pathways for CBD but it has yet to engage in rulemaking or issue guidance that would provide a clear framework under which FDA could maintain oversight over CBD to ensure that its use in a range of products is safe.

Last week, FDA posted a letter it recently sent to a dietary supplement company, which explained its concerns about the adequacy of safety evidence the company presented to demonstrate that the use of CBD as a new dietary ingredient will reasonably be expected to be safe. This latest message adds to the confusion surrounding the legal status of CBD and raises questions about whether FDA will continue to exercise enforcement discretion with regard to products containing CBD, particularly dietary supplements.

FDA's Primary Focus on Therapeutic Claims

Meanwhile, consumer demand for CBD is strong, and the market is already flooded with products that contain CBD. CBD is everywhere. CBD is present in a variety of food products, dietary supplements, cosmetics, vape products, and pet products, many of which are being marketed for a host of therapeutic uses. Taking products marketed for therapeutic uses as an example, some products claim to treat teething pain and earaches in infants, while others claim to treat psychological, neurological, or cognitive conditions such as depression, anxiety, attention-deficit/hyperactivity disorder (ADHD), as well as autism, Parkinson's and Alzheimer's disease.

FDA is aware of the widespread prevalence of such products, "recognizes the potential opportunities" that cannabis or cannabis-derived compounds may offer, and "acknowledges the significant interest in these possibilities."[1] Nevertheless, FDA has concerns about the safety and quality of products containing cannabis-derived compounds, including CBD, because the products have not been subject to FDA review for safety and efficacy. FDA has thus far only approved one prescription drug product that contains a purified form of CBD, Epidiolex, for the treatment of two rare and severe seizure disorders.

FDA has issued a number of warning letters to companies that have sold CBD products for therapeutic purposes under the theory that marketing such products without an approved new drug application (NDA) or without conforming to an over-the-counter (OTC) drug monograph violates the Federal Food, Drug, and Cosmetics Act (FDCA). This is not at all surprising and is consistent with FDA's practice with respect to any products that claim to prevent, diagnose, mitigate, treat or cure various diseases or products (other than food) that are intended to affect the structure or function of the body.

CBD in Dietary Supplements and Food

Notably, FDA has also issued enforcement letters warning that they determined CBD products are excluded from the definition of "dietary supplement" under the FDCA because CBD is the active ingredient in Epidiolex, an approved prescription drug product. In general, products are not considered dietary supplements under the FDCA if they include any article that is (1) an active ingredient in an approved drug product or (2) under investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.[2] There is an exception: a dietary supplement can include such an article if it was marketed as a dietary supplement or food before the new drug investigations were authorized. However, FDA has concluded that "this is not the case for CBD."[3]

FDA has followed a similar approach with respect to the use of CBD in food. The FDCA defines "food additive" as any substance the intended use of which results in its becoming a component of any food, unless the substance is generally recognized as safe (GRAS) among

qualified experts under the conditions of its intended use, or unless the substance meets one of the exceptions listed in the statute.[4] Food additives require premarket approval based on a demonstration that the substance can be used safely in food. CBD has not been approved as a food additive. FDA has determined that there lacks sufficient scientific information to support the safety of CBD in food, so it is unable to conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food.[5]

Therefore, FDA considers any food that includes CBD to be adulterated, the introduction/delivery for introduction of which into interstate commerce is a prohibited act under the FDCA.

Status of FDA's Enforcement Policy

In light of these determinations, FDA takes the position that products with CBD cannot be marketed as or in dietary supplements or food, regardless of whether the products are promoted for therapeutic uses. FDA's enforcement activities have nevertheless focused on companies that make therapeutic claims about their CBD products or products that otherwise pose a greater risk to consumers.[6] In response to a directive from congressional appropriators, FDA reported to Congress in July 2020 that it has the authority to allow products containing CBD to be sold legally as dietary supplements and was developing a "risk-based enforcement policy that would provide greater transparency and clarity regarding FDA's enforcement priorities while FDA potentially engages in the process of a rulemaking."[7] FDA had submitted a draft guidance document on its CBD enforcement policy to the White House Office of Management and Budget (OMB) last July, but OMB withdrew the policy when the Biden administration took office to allow the agency to review and reconsider.

Congressional Interest in FDA's Regulation of CBD is Growing

Congressional appropriators have again directed FDA to focus on CBD. Senate appropriators have directed FDA to maintain funding levels to support regulatory activities, including the review of product applications, enforcement, and targeted research for cannabis-derived substances. In addition, the Senate directs FDA to issue its enforcement discretion policy regarding CBD and maintain the policy in effect until the agency establishes a regulatory process for the use of CBD in products. FDA is also encouraged to consider existing ongoing medical research related to CBD and ensure that future regulatory activity does not discourage the development of new drugs.[8] The House also passed a spending funding bill last month that included an amendment asking FDA to initiate rulemaking and issue guidance on the use of CBD in foods and dietary supplements.[9]

Some lawmakers have drafted or introduced bills to create a legislative framework under which CBD can be included in foods and dietary supplements rather than wait for the FDA to initiate rulemaking. One proposed bill, the Cannabis Administration and Opportunity Act, would remove cannabis from the list of controlled substances in the Controlled Substances Act and would create a new Center for Cannabis Products at the FDA to regulate cannabis. The regulatory scheme would include requirements related to good manufacturing practices, product standards, registration and listing, labeling, and directions for use. The bill would also require FDA to expedite development of certain cannabis-based drugs and it would create a legal pathway to allow CBD in dietary supplements while providing FDA with more enforcement authority over non-compliant products. A separate bill would allow hemp-derived cannabidiol and any other hemp-derived ingredient to be legally used as a dietary ingredient in dietary supplements, provided that the product meets all other applicable requirements for a dietary supplement under the FDCA.[10]

FDA's Refusal to Accept CBD as a New Dietary Ingredient

FDA has recently signaled that it has not yet seen enough evidence to permit CBD to be used in dietary supplements. A manufacturer or distributor of a dietary supplement that contains a new dietary ingredient (NDI) that that has not been present in the food supply as an article used for food can submit a notification to FDA with information to support the manufacturer's conclusion that a dietary supplement with that NDI will reasonably be expected to be safe.[11] The manufacturer is required to submit the notification at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce. If the FDA acknowledges without objection, the company can proceed to distribute the dietary supplement in interstate commerce.

Charlotte's Web, Inc. submitted an NDI notification concerning its full spectrum hemp extract (a CBD product), which it intended to market in a dietary supplement tincture. FDA responded to the notification, reiterating its position that CBD products are excluded from the definition of dietary supplement under the FDCA.[12] FDA also objected to the notification because it had concerns about the adequacy of the safety evidence included in the submission and decided that the company failed to provide an adequate basis to conclude that a dietary supplement containing the ingredient would reasonably be expected to be safe when used under the proposed conditions of use. The letter concluded that any dietary supplement containing the NDI "may be adulterated" under the FDCA.

Charlotte's Web undertook the task of gathering evidence and putting together an NDI submission for its extract and was rewarded with a letter from FDA notifying the company that it cannot use the extract in dietary supplements. Yet, there are countless of other dietary supplements that contain CBD on the market, and none of them have an NDI that has been acknowledged by the FDA without objection.

FDA's letter to Charlotte's Web was in response to the NDI notification that the company submitted about its specific extract, but the communication has implications that extend to all dietary supplements that include CBD. The letter provides insight into the level of data that FDA expects in order to establish that a dietary supplement containing CBD is reasonably expected to be safe. The letter also reveals that FDA is not close to undertaking a rulemaking that would provide an exception to the statutory prohibition and that a legislative solution may ultimately be necessary for CBD to be legally used in dietary supplements. Since FDA has yet to release a formal enforcement discretion policy, dietary supplements with CBD currently face a higher risk of enforcement. So, dietary supplement companies that continue to market their CBD products should be extra mindful of the claims they make about their products.

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[1] U.S. Food & Drug Admin., FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd.

[2] FDCA § 201(ff) (21 U.S.C. § 321(ff).

[3] See, e.g., U.S. Food & Drug Admin., Warning Letter to KOI CBD LLC (Nov. 22, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/koi-cbd-llc-593391-11222019.

[4] FDCA § 201(s) (21 U.S.C. § 321(s)).

[5] Warning Letter to KOI CBD LLC, supra note 3.

[6] See, U.S. Food & Drug Admin., Press Release, "FDA Advances Work Related to Cannabidiol Products with Focus on Protecting Public Health, Providing Market Clarity" (Mar. 5, 2020), https://www.fda.gov/news-events/press-announcements/fda-advances-work-related-cannabidiol-products-focus-protecting-public-health-providing-market.

[7] U.S. Food & Drug Admin., Rep. to H. Comm. on Appropriations & S. Comm. on Appropriations—Cannabidiol (CBD)—Report in Response to Further Consolidated Appropriations Act, 2020.

[8] S. Rep. No. 117-34, S. 2599, 117th Cong. (2021).

[9] H. Rep. No. 117-109, H.R. 4502, 117th Cong. (2021).

[10] Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020, H.R. 8179, 116th Cong. (2020).

[11] FDCA § 413 (21 U.S.C. § 350b).

[12] U.S. Food & Drug Admin., Letter from Office of Dietary Supplement Programs to Charlotte's Web, Inc. (Jul. 23, 2021), Docket No. FDA-2021-S-0023, https://www.regulations.gov/document/FDA-2021-S-0023-0053.

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