Health Policy and Legislation Alert

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FDA Harshes the CBD Buzz; is it High Time for Congress to Step In?

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Yesterday, the U.S. Food and Drug Administration (FDA) announced the conclusion of an internal working group that cannabidiol (CBD) will require a new regulatory pathway. The FDA explicitly denied three citizen petitions urging the agency to conduct rulemaking to allow CBD to be marketed as a dietary supplement, determining that the available evidence does not sufficiently demonstrate that CBD can meet the safety standards for dietary supplements or food additives. The FDA stated that it would work with Congress to develop a cross-agency strategy to regulate products containing CBD.

CBD has increasingly been added to food products in recent years, appearing in everything from mints to lattes, despite never being determined to be "generally recognized as safe" (GRAS) for human consumption by the FDA and being an ingredient in an FDA-approved drug.[1] CBD, like tetrahydrocannabinol (THC), is a cannabinoid that can be derived from cannabis plants, including hemp. The 2018 Farm Bill removed hemp and its compounds from the federal controlled substances list, thereby establishing a commercially-available source of CBD.

In 2018, the FDA approved a drug containing CBD, derived from marijuana, indicated for treatment of certain forms of epilepsy. Under existing law, an active ingredient of an approved drug is not eligible to be used as a food ingredient unless one of several exceptions applies, including a determination by the Secretary, via regulation after notice and comment, that the drug (i.e. the active ingredient) can be used in food.[2] The Secretary has not made such a determination. Furthermore, the FDA has previously stated that it considers CBD's status as an active ingredient in an approved drug as well as its lack of recognition as GRAS to be individually sufficient grounds to determine that CBD is an unapproved food additive.[3]

Though yesterday's decision might have been a surprise to some industry-members, the FDA has not stood idle when it comes to products containing CBD. The agency has taken action against some CBD-product manufacturers, particularly when a product is accompanied by a drug claim ("any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug"). It remains to be

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seen if the FDA's determination will lead to additional enforcement actions against CBD-containing products marketed as foods.

Given the complexity of regulation in this area, as well as the specter of a scheduling change for marijuana,[4] it is possible that the agency is looking for an opportunity to address both fronts through a legislative effort. Key lawmakers on both sides of the aisle have taken interest in the FDA's approach to CBD. In July 2022, Senate Majority Leader Chuck Schumer (D-NY), Senate Finance Committee Chair Ron Wyden (D-OR), and Sen. Cory Booker (D-NJ) introduce cannabis reform legislation that included provisions intended to provide a pathway to federal regulation of CBD by the FDA. In September 2022, Reps. Brett Guthrie (R-KY) and Morgan Griffith (R-VA)—now chairs of the House Energy and Commerce Committee Health Subcommittee and Oversight & Investigations Subcommittee, respectively—sent a letter urging the agency to establish clear regulatory standards for CBD and CBD-derived products. Sen.Wyden (D-OR) also has raised concerns about the current regulatory uncertainty around CBD. The latest announcement from the FDA is expected to further heighten congressional focus in this area. While it remains uncertain how Congressional interest may translate into legislative action, it is certain that stakeholders will be watching for any legislative developments as the 118th Congress continues to unfold.

[1] The agency has also previously stated that CBD's status as an active ingredient in an FDA-approved drug means that it does not comply with the definition of a dietary supplement. See also, 21 U.S.C. § 321(ff)(3)(B) (dietary supplement); 21 U.S.C. § 331(ll) (food additive).

[2] 21 U.S.C. § 331(ll)(2).

[3] The FDA has also acknowledged that ingredients derived from cannabis that do not contain CBD or THC may be able to be used in foods and dietary supplements. For example, in 2018 the FDA determined that hulled hemp seed, hemp seed protein powder, and hemp seed oil (all derived from hemp seeds) were safe for human consumption.

[4] In late 2022, President Biden instructed the FDA and the Department of Health and Human Services to review the current listing policy for marijuana.

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