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Client Alert

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FDA Rejects Bids To Market CBD-Based Dietary Supplements

On July 23, 2021, the U.S. Food and Drug Administration ("FDA" or "Agency") rejected two New Dietary Ingredient ("NDI") notifications to market full-spectrum cannabidiol ("CBD") as part of dietary supplements.[1] This move signals that FDA does not believe there is a clear regulatory pathway to market CBD products in the United States, despite the fact that the global CBD market is expected to reach $13.4 billion by 2028.[2]

BACKGROUND

The 2018 Farm Bill explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds, including CBD. Generally, FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products, meaning that they are subject to the same authorities and requirements as FDA-regulated products containing any other substance.

The Federal Food, Drug, and Cosmetic Act ("FD&C Act") requires that manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" notify FDA about these ingredients.[3] A "new dietary ingredient" is an ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered. Generally, the notification must include information showing that there is a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the condition recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe.[4] If FDA determines that this requirement is not met,[5] then the dietary supplement is considered to be adulterated because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.[6]

In March 2021, Charlotte's Web and Irwin Naturals—which sell CBD-based oils and capsules—filed NDIs to market their own "Full Spectrum Hemp Extracts" as dietary supplements. They did so, notwithstanding the fact that FDA had already concluded that CBD could not be used in dietary supplements.[7] The Agency's position then and now is that CBD—

whether in an isolate form, full-spectrum form, or broad-spectrum form—does not meet the statutory definition of "dietary supplement" because of the FD&C Act's dietary supplement exclusion provision, which excludes from the definition any substance that (1) is an active ingredient in an FDA-approved drug product or (2) has been authorized for investigation as a new drug (i.e., is the subject of an investigational new drug application).[8] The definition excludes CBD because that ingredient is the active pharmaceutical ingredient in at least one approved pharmaceutical drug product (Epidiolex), and substantial clinical investigations regarding CBD have been made public. While there is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, FDA had concluded that this is not the case for CBD.[9]

FDA UNSURPRISINGLY REJECTS THE NDIS

Given its previous position, it is not surprising that FDA rejected Charlotte Web's and Irwin Natural's NDIs. In July, FDA sent letters to the two companies, determining that their Full Spectrum Hemp Extracts could not be used in dietary supplements pursuant to the dietary supplement exclusion provision, discussed above. FDA spelled out exactly what it meant: the product "may not be marked as or in a dietary supplement."[10]

Notably, FDA explained that the companies' notifications did not provide an adequate basis to conclude that the products would reasonably be expected to be safe. FDA concluded that *even if* CBD was not excluded from the definition of dietary supplement, the Agency still had "concerns about the adequacy of safety evidence" that the companies had submitted.[11] The Agency noted that the companies' submissions relied on deficient categories of evidence; their evidence of the history of use was insufficient and/or vague; and their studies were unreliable.[12] It also determined that none of the clinical and pre-clinical studies that the companies provided adequately addressed reported toxicity endpoints of CBD, such as hepatotoxicity and reproductive toxicity.[13]

CONGRESS WILL NEED TO INTERVENE

FDA's letter highlights that, until Congress intervenes, the CBD-products market remains on shaky legal footing. The timing could not be better, as Congress is currently considering two bills that would affect the regulation of CBD-infused products. In February, a bipartisan group of representatives introduced the Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2021, which, if enacted, would allow the use of hemp-derived CBD in dietary supplements. In addition, a bipartisan group of senators introduced the Hemp Access and Consumer Safety Act. If enacted, the Senate bill would allow hemp-derived CBD products to be lawfully used in dietary supplements, food, and beverages. But unfortunately, until Congress enacts a bill, this profitable market will likely remain in an uncertain position.

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[1] *There are three main types of CBD. CBD isolate is the pure form of CBD, while full-spectrum CBD is an extract containing other compounds of the cannabis plant, such as terpenes and other cannabinoids. The third type is broad-spectrum CBD, which contains many cannabis plant compounds.*
[2] *See Global $13.4 Billion Cannabidiol Market to 2028—Increasing Awareness [of] CBD Health Benefits, Changing Consumer Opinion, and Attitude Toward CBD Products* (Mar. 24, 2021), https://www.prnewswire.com/news-releases/global-13-4-billion-cannabidiol-market-to-2028---increasing-awareness-cbd-health-benefits-changing-consumer-opinion-and-attitude-toward-cbd-products-301254807.html.
[3] *See* 21 U.S.C. § 350b(a).
[4] *See* FDA, *New Dietary Ingredients (NDI) Notification Process* (updated Dec. 16, 2019), https://www.fda.gov/food/dietary-supplements/new-dietary-ingredients-ndi-notification-process.
[5] *See* 21 U.S.C. § 350b(a)(2).
[6] *See id.* § 342(f)(1)(B).
[7] *See id.* § 321(ff)(3)(B).
[8] *See id.* § 321(ff)(3)(B).
[9] *See* FDA, *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)* (updated Jan. 22, 2021) (Question 9), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#dietarysupplements.
[10] *See* Letter from Cara Welch, Ph.D., Acting Director, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, FDA, to Tim Orr, Charlotte's Web, Inc. (July 23, 2021), *available at* FDA, *75-Day Premarket Notification for New Dietary Ingredients 2021*, Docket No. FDA-2021-S-0023-0053 (posted Aug. 11, 2021), https://www.regulations.gov/document/FDA-2021-S-0023-0053; Letter from Cara Welch, Ph.D., Acting Director, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, FDA, to Irwin Naturals (July 23, 2021), *available at* FDA, *NDI 1199 - Full-Spectrum Hemp Extract (FSHE) from Irwin Naturals*, Docket No. FDA-2021-S-0023-0050 (posted Aug. 11, 2021), https://www.regulations.gov/document/FDA-2021-S-0023-0050.
[11] *Id.*
[12] *Id.*
[13] *Id.*