Council for Responsible Nutrition

Hemp-Derived CBD
Dietary Supplement Position

DECEMBER 2020

THE COUNCIL FOR RESPONSIBLE NUTRITION (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 190+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers.[1]

CRN members include manufacturers and suppliers that sell hemp-derived cannabidiol (CBD) dietary supplements around the country and therefore have a vested interest in having hemp-derived CBD dietary supplements consistently regulated by existing federal standards for dietary supplements.

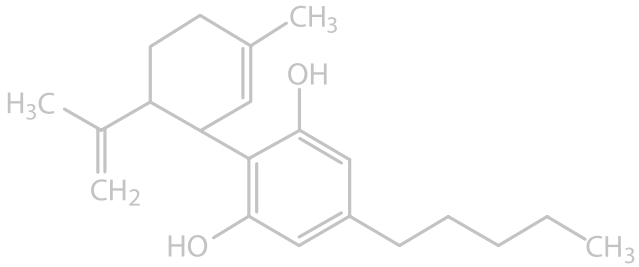
Particularly concerning is the possibility of inconsistent and perhaps conflicting state requirements on the regulation of hemp-derived CBD products, including dietary supplements, that contribute to a patchwork of state laws that make simultaneous compliance with anticipated federal regulations difficult if not impossible.

[1] In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit www.crnusa.org. Follow us on: Twitter @CRN_Supplements, and LinkedIn.

CBD Background

Cannabis is a plant of the *Cannabaceae* family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Parts of the *Cannabis sativa* plant have been controlled under the Controlled Substances Act since 1970 under the drug class, "Marihuana" (commonly referred to as "marijuana").[2] THC is regarded as the primary psychotropic component of cannabis that is responsible for the feeling of being "high." In contrast, CBD generally is understood to not be intoxicating.

At the federal level, the Agriculture Improvement Act of 2018, (commonly referred to as the 2018 Farm Bill) was signed into law on December 20, 2018.[3] This law changed certain federal authorities relating to the production and marketing of hemp, defined in the Act as, "the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."[4] These changes include removing hemp from the Controlled Substances Act, which means that cannabis plants, derivatives, and products derived from these plants that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.[5]



Cannabidiol

The 2018 Farm Bill explicitly preserved the federal Food and Drug Administration's (FDA) authority to regulate products containing hemp or hemp-derived compounds under the Food Drug and Cosmetic Act and section 351 of the Public Health Service Act. Products containing hemp or hemp-derived compounds are FDA-regulated products and are subject to the same authorities and requirements as FDA-regulated products containing any other substance.[6]

[2] See, 21 U.S.C. 802(16).

[3] See, Agriculture Improvement Act of 2018, Pub. L. 115-334.

[4] See, Sec.297A. Definitions, (1) "Hemp", Pub. L. 115-334.

[5] See, Pub. L. 115-334, Sec. 12619(a).

[6] See, FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD). See also, Pub. L. 115-334, Sec. 297D ("(c) EFFECT ON OTHER LAW.–Nothing in this subtitle shall affect or modify– … (3) the authority of the Commissioner of Food and Drugs and the Secretary of Health and Human Services– (A) under– (i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or (ii) section 351 of the Public Health Service Act (42 U.S.C. 262)….).

At present, FDA has concluded that CBD is excluded from being a permissible ingredient in dietary supplements due to a provision in the definition of "dietary supplement" in section 201(ff) of the Food, Drug & Cosmetic Act. Section 201(ff)(3)(B) excludes an ingredient from being used in a dietary supplement if that ingredient was an "article" that was either: (1) "approved as a new drug, under section 355 of this title" or (2) "authorized for 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" and (3) "which was not before such ... authorization marketed as a dietary supplement or as a food…".[7] That statutory exclusion of section 201(ff)(3)(B) applies unless FDA, in the agency's discretion, "has issued a regulation, after notice and comment, finding that the article would be lawful under [the Food Drug and Cosmetic Act.]" At present, FDA has not exercised that discretion with respect to CBD, although CRN, along with several other organizations, have petitioned the agency to do so.[8]

Congress enacted section 201(ff)(3)(B) to protect commercial interests of pharmaceutical research to incentivize drug development—not because of any safety concerns about the use of an ingredient in both dietary supplements and drugs.[9] Starting immediately after the passage of the 2018 Farm Bill, FDA has taken the position that hemp-derived CBD cannot be a dietary supplement because the agency determined that CBD was the subject of substantial clinical investigations as a drug (Epidiolex) that were made public prior to CBD's use in supplements.[10]

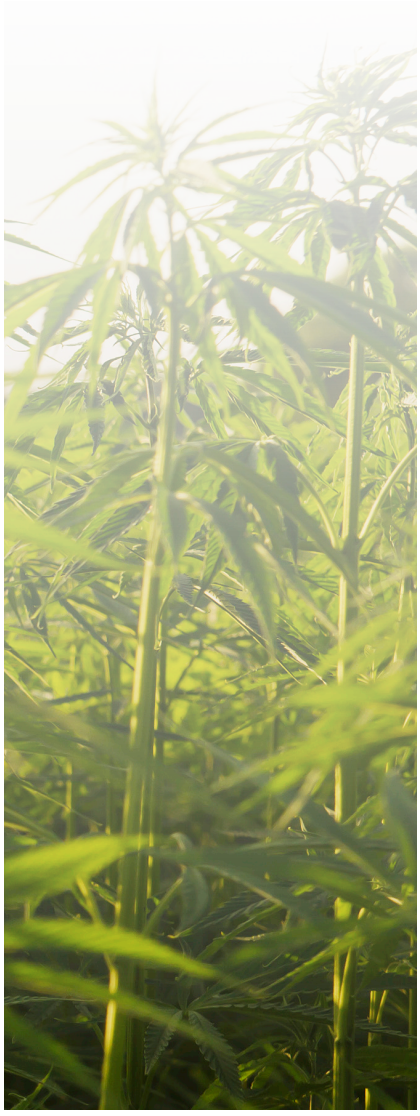
[7] Codified at 21 U.S.C. 321(ff)(3)(B).
[8] See, CRN Citizen Petition to FDA.
[9] See, e.g., S. Rep. 103-410, Part V, § 3 (1994); 140 Cong. Rec. S11709 (daily ed. Aug. 13, 1994).
[10] See, FDA Guidance, FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers.

CBD Marketplace Blossoms Despite FDA

In the intervening time since December 2018, the marketplace for CBD and consumer interest in the ingredient has exploded. More than 20 million Americans report using hemp-derived CBD dietary supplements.[11] The Nutrition Business Journal estimates that sales of hemp CBD-based products will reach $4 billion by 2023, and that the channel dynamics will shift rapidly in the market over the next few years.[12] Millions of Americans continue to take CBD dietary supplements and many supplement users specifically cite taking CBD to support mental health (16%) and sleep health (17%), according to the 2020 CRN Consumer Survey on Dietary Supplements.[13] Further, CRN's COVID-19 Survey on Dietary Supplements found that a subset of supplement users, those who indicated increasing their supplement routine throughout the pandemic, reported increasing their intake of CBD.[14] CBD is an ingredient that continues to be at the forefront of consumer interest.

The blossoming market for CBD, combined with FDA's failure to establish a comprehensive federal framework to regulate CBD as an over-the-counter product, have produced a patchwork of state regulations and a chaotic marketplace. FDA, the Federal Trade Commission (FTC) and consumer watchdog groups have identified bad actors marketing products with unsubstantiated claims for their CBD products' roles in preventing, diagnosing, treating, or curing a number of diseases or conditions. Acting FDA Commissioner Ned Sharpless, M.D. stated in an October 22, 2019, FDA News Release, "This is especially concerning when companies are peddling unproven CBD products for use in vulnerable populations like infants and children."

The *Nutrition Business Journal* estimates that sales of hemp CBD-based products will reach $4 billion by 2023.



[11] See, CRN Update: As More Consumers Seek Supplements to Support Health During COVID-19 Pandemic, CBD Regulation Is More Critical Than Ever.

[12] See, The Analyst's Take: Mass market sales of hemp CBD projected to spike in 2020.

[13] See, 2020 CRN Consumer Survey on Dietary Supplements.

[14] See, CRN's COVID-19 Survey on Dietary Supplements .

He continued, "We've sent numerous warning letters that focus on matters of significant public health concern to CBD companies, and these actions should send a message to the broader market about complying with FDA requirements. As we examine potential regulatory pathways for the lawful marketing of cannabis products, protecting and promoting public health through sound, science-based decision-making remains our top priority. We appreciate the FTC joining us on these and other actions to protect consumers from fraudulent CBD products."

Because of continued federal inaction, consumers remain at higher risk of dangerous products in the market that fail to adhere to the significant body of dietary supplement law and regulation. FDA's lethargy and delay with respect to the legality of CBD make it difficult for consumers to distinguish between responsible players and those bad actors who see a potential profit by flouting standards for quality, sourcing, manufacturing, advertising and claims. A lack of federal regulation also discourages much-needed research and prompts states to fill in the federal regulatory gaps by creating a patchwork of burdensome and inconsistent state regulation.

COVID-19 Impacts

This seemingly unregulated market has been further accelerated by this unprecedented COVID-19 pandemic. Consumers already predisposed to favor supplementation are turning to these products in even greater numbers to support their health and wellness during the crisis. Particularly during the COVID-19 pandemic, CBD has sustained relevance with consumers as the public seeks support to manage their mental health, well-being, and sleep. This consumer attention further emphasizes how critical it is to create a legal pathway to market for hemp-derived CBD-containing dietary supplements.

CBD products are also receiving a disproportionate share of warning letters from FDA for impermissible claims to treat, cure or prevent COVID-19. Bad actors identified for promoting illegal products claiming to treat, cure or prevent COVID-19 are not confined to any one ingredient or class of products, but recent warning letters from FDA reveal no shortage of CBD products making claims about coronavirus.[15] Both phenomena, surging consumer curiosity and rampant false marketing of claims, create an urgency for FDA to create certainty in the market.

[15] See, Warning Letters and Test Results for Cannabidiol-Related Products.

CRN's Federal Action

A comprehensive framework of CBD regulation is even more critical to protect the safety of consumers. This is why CRN has worked with Congressional leaders and staff to support introduction of federal legislation, H.R. 8179, the Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020.[16] This legislation, if enacted, bypasses the obstacle of the drug preclusion provision in section 201(ff), discussed above, and will provide a legal pathway to market for dietary supplements containing hemp-derived CBD. The legislation provides that despite waiving the drug preclusion language, products marketing CBD in a dietary supplement must comply with, "all other applicable requirements for a dietary supplement in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.)".

It is CRN's position that state hemp-derived CBD regulations, even in the current absence of federal direction, should establish or maintain a regulatory framework consistent with the federal approach for dietary supplements.

Even as states step into the role of implementing their own regulation of hemp-derived CBD, they should be mindful of the federal requirements for dietary supplements as a federal framework for CBD products as anticipated federal regulation will likely incorporate these requirements as well.

Therefore, **it is CRN's position that state hemp-derived CBD regulations, even in the current absence of federal direction, should establish or maintain a regulatory framework consistent with the federal approach for dietary supplements.** The current federal regulatory structure for dietary supplements is robust and comprehensive. State laws and regulations consistent with the federal framework will appropriately protect consumers and ensure companies are not left to navigate a patchwork of state regulations once a federal pathway is developed.

[16] Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020.

Federal Regulatory Structure for Dietary Supplements

The FDA and the FTC already extensively regulate dietary supplements at the federal level in the United States. The Dietary Supplement Health and Education Act (DSHEA), a federal law enacted in 1994, established a federal regulatory structure for dietary supplements, and provides the FDA with substantial authority to protect consumers.

Current dietary supplement regulations cover all aspects of supplement manufacturing and distribution, from safety of ingredients, to manufacturing process requirements, to product claims. These comprehensive regulations ensure supplement products are safe and marketed to consumers in a truthful manner:

Safety Standards. Current laws require that manufacturers ensure all dietary ingredients are safe. A dietary supplement is considered adulterated if it presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested on the product label.[17] FDA has the authority to remove adulterated and misbranded products from the marketplace. Further, FDA has extensive authority to review a company's safety determination before a product is made available to consumers. For example, a manufacturer using any dietary ingredient that was not used before the passage of DSHEA in 1994 must submit notification and safety information to FDA at least 75 days before introducing the new ingredient to market.[18]

Good Manufacturing Practices. In addition to ensuring ingredient safety, supplements are subject to extensive requirements governing product manufacturing.[19] All persons that import, export, manufacture, package, label, or hold a dietary supplement are required to adhere to federal Good Manufacturing Practices (GMPs). The GMP rules set minimum requirements on manufacturer personnel, facilities, equipment and utensils used, production and process controls, including mandatory testing of ingredients and finished products, packaging requirements, identification and quarantine of returned supplements, and the investigation of product complaints by companies and FDA.[20]

[17] See, 21 USC §342(f).
[18] See, 21 USC §350b.
[19] See, 21 USC §342(g).
[20] See, 21 CFR Part 111.

Adverse Event Reporting. Supplement regulations extend past pre-distribution measures and require that companies monitor supplement complaints to ensure continued safety. In 2006, the dietary supplement industry helped pass the Dietary Supplement and Nonprescription Drug Consumer Protection Act, which created a post-market surveillance program that requires supplement companies to monitor and investigate consumer adverse events, and submit information about serious adverse events to FDA.[21]

Labeling. Dietary supplements must be properly labeled to be marketed in the United States.[22] All dietary supplement labels must include a statement of identity; the net quantity of contents; nutrition labeling, including the Supplement Facts panel; a complete list of product ingredients; and the name and place of business of the manufacturer, packer, or distributor. Failure to include all the required information allows FDA to deem the product misbranded.

Advertising. Any claims made that are not substantiated and consistent with both FDA and other regulatory requirements cause a product to be misbranded. FDA shares jurisdiction over supplement claims with the FTC at the federal level and state attorneys general. The FTC regulates against false and misleading claims, including online and social media, and has a long history of enforcement action against dietary supplement manufacturers, distributors, marketing companies, and retailers.

Companies that run afoul of these requirements can be subject to a host of repercussions, including injunctions halting business and product distribution, product recalls, product seizures, fines and criminal penalties, consumer redress mandates, and even prohibitions against future advertising and conduct in an entire product category or industry.

[21] See, 21 USC §379aa-1.
[22] See, 21 USC §343(r)(6).

By creating a consistent, harmonized framework, states will encourage companies to develop high quality products that can be sold interchangeably from state to state.

Conclusion

Even in the absence of a single federal framework of regulation for CBD products, states imposing their own requirements and restrictions have the opportunity to model these regulations after the federal requirements for dietary supplements. By creating a consistent, harmonized framework, states will encourage companies to develop high quality products that can be sold interchangeably from state to state.

CRN will continue to urge FDA to open the dietary supplement lane to CBD, so that companies manufacturing and marketing CBD products are subject to the comprehensive range of dietary supplement laws and regulations. In the meantime, states have the opportunity to fill that vacuum with their own regulatory frameworks that are modeled on the federal approach. The health and safety of consumers must be the highest priority for the dietary supplement industry.