Council for Responsible Nutrition
1828 L Street, NW, Suite 810 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

September 1, 2021

The Honorable Charles Schumer
Majority Leader
United States Senate
Washington, DC 20510-3203

The Honorable Ron Wyden
United States Senate
221 Dirksen Senate Office Building
Washington, DC 20510-3703

The Honorable Cory Booker
United States Senate
717 Hart Senate Office Building
Washington, DC 20510-3007

Dear Senators Schumer, Booker, and Wyden:

The Council for Responsible Nutrition (CRN)[1], the leading trade association representing dietary supplement manufacturers and ingredient suppliers, writes today to offer our comments concerning your draft legislation - the Cannabis Administration and Opportunity Act - that would decriminalize marijuana and further regulate cannabis. More specifically, we offer comments only to provisions found in Section 505 of the Discussion Draft that relate to the regulation of hemp-derived cannabidiol (CBD) in dietary supplements.

Brief Overview

In December 2018, Congress enacted the Agricultural Improvement Act (2018 Farm Bill), which removed hemp, defined as cannabis (Cannabis sativa L.) and derivatives of cannabis with extremely low concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC) (no more than 0.3 percent THC on a dry weight basis), from the definition of marijuana in the Controlled Substances Act (CSA).

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 190 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

The intent of this legislation was to create a legal path for the sale of hemp and hemp-derived substances in a variety of products, including products regulated by the FDA, such as dietary supplements. However, based on a provision known as "drug preclusion" in the Food, Drug and Cosmetic Act (FDCA), explained in more detail below, the U.S. Food and Drug Administration (FDA) has taken the position that certain hemp-derived substances, such as cannabidiol (CBD) cannot be used in dietary supplements without further rulemaking by the agency. Nearly three years after passage of the 2018 Farm Bill, the FDA has yet to promulgate any clear regulation that would allow products containing hemp-derived CBD to be sold as dietary supplements. For the past almost three years, CRN has worked with congressional leaders to develop legislation that would remedy this situation and provide the agency with a clear directive to treat CBD as a dietary supplement.

In June 2020, CRN filed a citizen petition[2] requesting that FDA exercise its statutory authority to establish a regulation under which hemp-derived CBD may be legally marketed as a dietary supplement, clarify when a hemp-derived substance is subject to the drug preclusion provisions of 21 U.S.C. § 321(ff)(3)(B), and enforce existing dietary supplement regulations against hemp-derived CBD products already on the market. CRN's citizen petition outlines CRN's three requested actions with provided rationale. Since the submission of CRN's citizen petition, the House of Representatives has introduced bipartisan legislation twice, with the second and most current iteration taking the form of H.R. 841, also known as the Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act.

Your recently unveiled discussion draft proposal includes provisions that mirror those in the Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act. However, there are key differences between H.R. 841 and your discussion draft. CRN respectfully submits comments that will provide feedback and clarity for your further consideration, including:

- The importance of Congressional direction regarding the existing "Drug Preclusion" provision in the FDCA;
- Concerns with legislative direction for FDA to set a Maximum Safe Level via agency regulation; and
- Support for the language in H.R. 841, currently pending in the House of Representatives

Drug Preclusion Language

The drug preclusion provision of the Food, Drug and Cosmetic Act (FDCA) is a "race-to-market" provision designed to help protect drug development when a drug is approved (or substantially investigated) before a substance is marketed as a dietary supplement. If the supplement is already on the market prior to the entrance of the drug, the two products must coexist in the market (e.g., omega 3s, niacin and Vitamin D all currently can be found as supplements and as prescription drugs). However, if the drug arrives first—either by entering the market as an approved drug or having been studied in substantial, public, clinical investigations—the drug gets a monopoly on the article absent further FDA intervention.

Because of hemp's former designation as a controlled substance, dietary supplement companies could not even enter the market until December 2018 when Congress removed hemp from the CSA – well

[2] "Citizen Petition Requesting FDA Establish a Regulatory Pathway to Legally Market Dietary Supplements Containing Hemp-Derived Cannabidiol (CBD)," submitted June 16, 2020. To view the original document, go to: https://www.crnusa.org/sites/default/files/Daily/2020-06/CRN-CBD-Citizen-Petition061620.pdf

after a highly-purified, isolated form of CBD was studied and approved as the drug Epidiolex. FDA takes the position that this form of highly-purified isolate CBD prevents CBD from being used in dietary supplements, absent additional steps by the agency.

There are aspects of the existing law, however, that would allow FDA to remedy this situation by either: (1) construing the drug preclusion provision narrowly, as was original intended by Congress in the passage of the Dietary Supplement and Education Act (DSHEA), to permit other forms and dosages of CBD-containing products to be marketed as supplements; or (2) allowing CBD's use through notice and comment rulemaking, as contemplated by the FDCA. Both Congress and industry have repeatedly requested that FDA use its statutory authority to allow CBD to be a legal ingredient in dietary supplements, consistent with the intent of Congress in legalizing hemp. FDA has declined.

Specifically, under 21 U.S.C. § 321(ff)(3)(A), the law would exclude a particular article from the drug preclusion provision if "…the Secretary [of Health and Human Services], in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter." The agency has an opportunity to resolve these conflicts when they arise with a rulemaking that grants an exception to the statutory race to market. Therefore, even if the "article" is the same for both drugs and supplements, FDA could fix the problem.

Unfortunately, FDA has never exercised this rulemaking authority. The agency has also been unmoved by both congressional and industry leaders calling for it to provide much-needed statutory clarity as to what is the "article" under section 321(ff)(3)(A). As recently as July 2021, FDA submitted objection letters[3][4] to two major hemp dietary supplement manufacturers that submitted new dietary ingredient (NDI) notifications for full spectrum hemp products containing low-doses of CBD. Both letters state along similar lines that "FDA has concluded CBD products are excluded from the dietary supplement definition under 21 U.S.C. § 321(ff)(3)(B) (section 201(ff)(3)(B) of the Act). CBD is the active ingredient in the approved drug product, Epidiolex. Furthermore, the existence of substantial clinical investigations involving CBD has been made public. FDA has also determined that CBD was not marketed as a dietary supplement or conventional food before it was authorized for investigation as a new drug." And further, Senator Lee requested[5] the agency to conduct a public hearing on the agency's interpretation of the drug preclusion provision (in the context of another dietary ingredient) but on August 19th, FDA summarily denied that request[6].

The agency continues to incorrectly mischaracterize these full spectrum, low concentrate hemp products as the same article as a prescription drug containing one isolated substance and has ignored, dismissed, and downplayed ample evidence that these full spectrum hemp products can be marketed in a manner that is reasonably expected to be safe. Because of FDA's decision and willful inaction, the only pathway forward for legalizing CBD for dietary supplements falls to Congress to enact legislation that

---

[3] See "Letter from FDA CFSAN to Charlotte's Web, Inc. regarding NDI 1202 - Charlotte's Web Full Spectrum Hemp Extract (CW FSHE)," issued July 23, 2021. To view original letter, go to: https://www.regulations.gov/document/FDA-2021-S-0023-0053.

[4] See "Letter from FDA CFSAN to Irwin Naturals regarding NDI 1199 - Full-Spectrum Hemp Extract (FSHE)," issued July 23, 2021. To view original letter, go to: https://www.regulations.gov/document/FDA-2021-S-0023-0050.

[5] See "Letter to FDA re Part 15 Hearing," submitted on July 27, 2021. To view letter, go to: https://www.crnusa.org/sites/default/files/Daily/2021-08/Sen-Lee-Letter-FDA-NAC-0727.pdf.

[6] See "FDA Response Letter to Senator Mike Lee (R-UT)," issued on August 19, 2021. To view letter, go to: https://www.crnusa.org/sites/default/files/Daily/2021-08/FDA-response-rePart15Hearing082301.pdf.

would bypass the drug preclusion language and expressly make CBD legal in supplements. CRN applauds your Discussion Draft for accomplishing that objective.

FDA Maximum Level for Dietary Ingredients

CRN expresses concerns with the draft legislation's provision deeming dietary supplements as adulterated if they were to contain more than a level of CBD per recommended daily serving set by FDA. The passage of DSHEA in 1994 prohibits FDA from setting a maximum dosing level for a dietary ingredient in advance of the ingredient being brought to market. Rather, the law established a pathway for new dietary ingredient notifications (NDINs) by which ingredient and product manufacturers must demonstrate that their products are reasonably expected to be safe. That process intended FDA to evaluate safety on a product-by-product basis recognizing that the wide range of indications and claims, precautionary label statements, manufacturing processes and delivery forms all factor into whether a particular product is "safe." To authorize FDA to set a pre-market safety level for all CBD-containing products would ignore the diversity of the supplement market, would be precedent shattering, and would defy the intent of Congress when DSHEA was signed into law over a quarter of a century ago.

FDA does not need to establish a market-wide predetermined safe level of CBD before a legal pathway for CBD can be developed, as the regulatory framework already exists through the NDIN process to ensure the safety of a dietary supplement. Under the rubric of dietary supplement regulations, safety is intended to be addressed on a product-specific basis in the framework already carefully laid out by Congress and FDA. This framework permits FDA to address safety in the context of each unique delivery form, ingredient matrix (e.g., CBD isolate versus full spectrum hemp extract), dosage, labeling and directions for use, and other unique considerations for each product. The law requires that any ingredient not in the market prior to 1994 (as would be the case with all hemp-derived CBD-containing products), is subject to the NDI provisions of 21 U.S.C. § 350b, and that each unique manufacturer of such CBD-containing ingredient would be required to file its own NDI notification.

The New Dietary Ingredient notification process assures a product-specific review: it allows manufacturers to present their evidence of safety and persuade FDA that based on the purity, dosage, labeling and other factors for that product, it is reasonably expected to be safe. Once established in regulation, an upper safe level would be difficult for FDA to amend, and the marketplace could not adapt to new science that supports a higher serving amount because FDA set a too low safe level that is too cumbersome to change. In this respect, hemp-derived CBD is actually no different than any other herbal constituent that is already regulated by FDA, and Congress should treat CBD like any other herbal constituent.

Therefore, we urge you to re-consider the inclusion of this language, which runs against over a quarter-century of congressional and agency precedent, and remove this provision from any final version of the legislative proposal.

Support for H.R. 841

CRN would also like to take this opportunity to re-affirm our support for H.R. 841, the Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act. This legislation, which is pending consideration before the House Energy and Commerce committee, includes a number of provisions that align with current dietary supplement laws and ensure all safe hemp-derived ingredients can be used in supplements, as Congress intended under the 2018 Farm Bill. For example, H.R. 841 excludes hemp-

derived CBD and other cannabinoids from the drug preclusion language in the definition of a dietary supplement. This would ensure both CBD and other cannabinoid-containing dietary supplements could legally enter the market, despite any drug preclusion concerns that have arisen because of hemp's previous CSA status. The discussion draft legislation is limited only to CBD and does not include other cannabinoids such as CBG and CBN.

H.R. 841 would also reiterate that CBD products and makers of hemp extract products must comply with the existing comprehensive regulatory framework for dietary supplements, first established by DSHEA, which ensure products are deemed safe, and properly labeled and prepared using cGMPs (current good manufacturing practices). In addition to the NDIN requirements describe above, these products would be required to be properly labeled with a Supplement Facts panel, provide contact information for their manufacturer or distributor on the label, restrict their claims to avoid disease claims, submit serious adverse event reports to FDA, and register their manufacturing facilities with the agency. H.R. 841 recognizes that all these requirements and restrictions for dietary supplements imposed by law and regulation already would apply. Additional safety, manufacturing, and labeling requirements unique to CBD, such as setting predetermined safe levels, are unnecessary. This legislation has the bipartisan support of over 30 members of the House of Representatives and countless industry trade associations. We urge you to consider including H.R. 841's original language within your final proposal.

On behalf of our member companies, manufacturers, ingredient suppliers, and beyond, we thank you for your consideration of these comments, as well as your leadership on this important issue. We look forward to serving as a resource as you continue to work on drafting this legislation.

Sincerely,

Julia Gustafson
Vice President, Government Relations
Council for Responsible Nutrition

Steve Mister
President & CEO
Council for Responsible Nutrition