AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

September 1, 2021

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Via: Cannabis_Reform@finance.senate.gov

RE: Comments of the American Herbal Products Association Regarding the Cannabis Administration and Opportunity Act Discussion Draft

The American Herbal Products Association (AHPA) presents the following comments on the discussion draft of the Cannabis Administration and Opportunity Act[1] (CAOA) as publicly issued on July 14, 2021. AHPA's comments are focused on Section 505 ("REGULATION OF CANNABIDIOL") as presented in this discussion draft. This legislative proposal includes provisions relevant to the creation of a regulatory framework for cannabidiol (CBD) as a dietary supplement, described as follows in the summary[2] of the proposal:

> Sec. 505 of the Discussion Draft would create a legal pathway for cannabidiol (CBD) in dietary supplements. This section would amend the definition of "dietary supplement" to remove the prohibition on marketing CBD as a dietary supplement. Additionally, the section would deem dietary supplements to be adulterated if they contain more than a level of CBD per recommended daily serving set by the

[1] The full text of the "Cannabis Administration and Opportunity Act" discussion draft is available at this link: https://www.democrats.senate.gov/imo/media/doc/Cannabis%20Administration%20and%20Opportunity%20Act.pdf

[2] The text of the discussion draft summary is available at this link: https://www.democrats.senate.gov/imo/media/doc/CAOA%20Detailed%20Summary%20-.pdf

> Secretary. Certain dietary supplements would be required to submit New Dietary Ingredient (NDI) notifications to FDA. Additionally, the section would clarify that FDA would have the ability to require safety-related labeling or packaging requirements if needed and give FDA the ability to take enforcement action against any noncompliant CBD-containing products that is inappropriately labeled as a dietary supplement. Furthermore, the section would provide FDA with more comprehensive enforcement tools over products marketed as dietary supplements that contain articles that the sponsor intends to continue excluding from the definition of dietary supplement, such as synthetic (i.e., non-hemp derived) cannabidiol. These tools would help ensure that firms do not avoid the new requirements by simply developing their products with synthetic CBD rather than hemp-derived CBD.

AHPA is the national trade association and voice of the herbal products industry. AHPA's members include domestic and foreign companies doing business as growers, collectors, processors, manufacturers, marketers, importers, exporters, and distributors of herbs and herbal products. AHPA's members are engaged in the commerce of herbs and herbal products, including finished products such as teas and dietary supplements, plant extracts, and other ingredients used in such products as well as bulk botanical commodities. Relevant here, these herbs and herbal products include cultivars of *Cannabis sativa* L. and products derived therefrom that qualify as hemp under federal law.[3] AHPA's members therefore have an interest in the subjects of the CAOA discussion draft that relate to these cultivars of the plant species and various products derived from it.

AHPA has not offered comments on all elements in the CAOA discussion draft; absence of comments on any element or section of the CAOA discussion draft should not be taken to mean that AHPA agrees with such element or section, unless such agreement is specifically stated.

Lack of consistency with current Senate legislative proposal for CBD regulatory framework

AHPA notes that Section 505 of the CAOA discussion draft contains none of the text of the current Senate legislative proposal to establish a regulatory framework for hemp-derived CBD as well as other hemp-derived ingredients. AHPA has expressed its public support for the "Hemp Access and Consumer Safety Act," (S. 1698) introduced on May 19, 2021, by Senators Ron Wyden (D-OR), Jeff Merkley (D-OR), and Rand Paul (R-KY). This bill proposes to amend the

[3] The Agricultural Marketing Act of 1946, section 297A, defines hemp 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." 7 U.S.C. § 1639o(1).

Federal Food, Drug, and Cosmetic Act (FD&CA) by establishing exceptions to the statutory restrictions that have prevented the U.S. Food and Drug Administration (FDA) from setting clear regulatory frameworks for hemp and hemp-derived CBD that would assure consumer access. Importantly, the legislation would subject foods and dietary supplements containing these ingredients to all of the requirements and protections applicable under FDA's current food and dietary supplement regulatory frameworks.

Instead, Section 505 proposes a much more limited FDA regulatory framework that addresses hemp-derived CBD in dietary supplements only, and it does not address other hemp derivatives already in the consumer marketplace in both dietary supplement and food products. It also limits the options available for the demonstration of safety for hemp-derived CBD to use of NDI notifications and authorizes FDA to determine a daily serving limit for CBD, regardless of the data submitted by a marketer for FDA review.

Opportunity to redefine "hemp"

As the Sponsoring Offices requested comments regarding the definition of "cannabis" as proposed in the CAOA, AHPA believes this proposed legislation also provides a timely opportunity to improve the current federal definition of "hemp" to the benefit of both farmers and consumers. While the 2018 Farm Bill established the current definition of "hemp,"[3] farmers have been challenged to reliably meet the very stringent threshold of not more than 0.3 percent delta-9-tetrahydrocannabinol required by current law, leading to destruction of crops and loss of farm revenue when this threshold is exceeded.[4] The USDA Hemp Production Program does not recognize legal negligence for "hot" hemp crops that test at levels that do not exceed 1.0 percent delta-9-tetrahydrocannabinol, but it does require the destruction or disposal via acceptable processes for hemp crops that exceed the 0.3 percent delta-9 THC threshold.

The current federal regulations for hemp define a compliance threshold only for delta-9-tetrahydrocannabinol, which has led to the marketing of products containing delta-8-tetrahydrocannabinol and delta-10-tetrahydrocannabinol, cannabinoids that can be synthesized using hemp-derived cannabidiol and may be labeled as hemp products.[5] Some states have begun issuing regulations to control products containing these other tetrahydrocannabinols, in the absence of clear federal limits addressing these additional tetrahydrocannabinols in consumer

[4] *See, e.g.*, London Gibson, *20% of Indiana's Hemp Crop Was Destroyed Last Year Because It Had Too Much THC*, BEDFORD (IN) TIMES-MAIL (May 20, 2021); Zach Harris, *Over 40% of Arizona's Latest Hemp Crop Will Be Destroyed for Having Too Much THC*, merryjane.com (Jan. 22, 2020); Don Reid, *Little Information on the 2019 Hemp Crop*, THE DAILY REPORTER (Coldwater, MI) (Feb. 20, 2020).

[5] While these tetrahydrocannabinols can be produced by the hemp plant, they are normally present at levels too low to make extraction for use in consumer products commercially feasible.

products. AHPA has issued a guidance policy for its members discouraging the marketing of such products when identified as being derived from hemp.[6]

As the regulatory framework for hemp is separated into the oversight of agricultural production of hemp plant material by USDA and the oversight of processing and manufacturing into consumable forms by FDA, AHPA proposes to amend the current definition of hemp to better reflect these separate regulatory functions. At present, the definition of hemp does not distinguish between these phases and is not adequate to address the emerging market of hemp-derived products. AHPA proposes the following definition be established for hemp:

> (i) The plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof, whether growing or not, with a total tetrahydrocannabinol concentration of not more than 1.0 percent on a dry weight basis, and (ii) all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers produced from such plant that have a total tetrahydrocannabinol concentration of not more than 0.3 percent.

This proposed definition will allow for separate, appropriate compliance thresholds to be applied to hemp as a plant material and as a processed consumer product, by any route of consumption. The proposed threshold of a total tetrahydrocannabinol concentration of not more than 1.0 percent on a dry weight basis for plant material will provide additional flexibility for farmers, who will have greater confidence in producing compliant hemp crops that do not exceed the threshold currently recognized by USDA for negligence. Establishing a total tetrahydrocannabinol concentration of not more than 0.3 percent for finished forms will maintain the current federal compliance threshold at the level of consumer exposure, while also including the tetrahydrocannabinols not addressed in current federal limits, such as the delta-8 and delta-10 tetrahydrocannabinols, as well as the acid forms of each.

Comments specific to Section 505.

Limiting the scope of the prior-drug exclusion exception to hemp-derived cannabidiol [proposed amendment to 21 U.S.C. § 321(ff)(3)(B)]

The CAOA limits the scope of the legislative proposal to only hemp-derived cannabidiol, rather than "hemp, hemp-derived cannabidiol, or a substance containing any other ingredient derived from hemp" as proposed in S. 1698. AHPA does not support this scope limitation, which if enacted would result in continued regulatory uncertainty and confusion about the applicability of the prior drug exclusion (21 U.S.C. § 321(ff)(3)(B)) to all other non-CBD hemp constituents, both now and in the future. The proposed revision would exclude the numerous currently

[6] AHPA, June 2021. Guidance policy for marketing of concentrated delta-8 tetrahydrocannabinol, artificial, or synthesized cannabinoids. Accessible at https://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/2021_AHPAGuidance_policy_for_cannabinoids_Final.pdf.

marketed products containing other hemp phytocannabinoids, terpenes, and other naturally occurring constituents of hemp.

AHPA hereby requests and recommends that the scope of the proposed legislation include these additional hemp constituents to ensure that consumers may access dietary supplements containing such compounds that are subject to the robust regulatory framework that FDA already administers for this product category. Importantly, this framework ensures the safety of dietary supplements, including through enforced compliance with requirements for use of good manufacturing practices, labeling for recommended use, new dietary ingredient notifications (as applicable), and reporting of serious adverse events. This request is also consistent with the scope of the "Hemp Access and Consumer Safety Act" (S. 1698) as currently drafted.

Establishment of a daily cannabidiol serving limit [21 U.S.C. § 342 (Adulteration)]
The CAOA contains a provision that would allow FDA to establish a recommended daily serving limit for cannabidiol via the Interim Final Rule (IFR) process. It is AHPA's position that the existing provisions of the FD&CA, including the NDI framework and the obligation to provide in labeling all material information for the establishment of conditions of safe use for specific products, already ensure consumer safety for dietary supplement products, including those containing hemp-derived ingredients. These established provisions obviate the need for FDA to have specific limit-setting authority, for cannabidiol or other new ingredients. Granting such authority would also create an unnecessary statutory precedent and add a unique regulatory burden to this class of products. AHPA recommends that this provision be removed.

The discussion draft of the CAOA would preclude the Secretary of Health and Human Services from accepting any NDI notification (NDIN) for a product with conditions of use that exceed any CBD daily serving limit established pursuant to this authority. Further, it would allow the Secretary to consider "whether the review of new dietary ingredient notifications for products containing higher levels of cannabidiol may be unduly burdensome" in establishing a daily serving limit for CBD. AHPA notes that FDA does not have such latitude to decline to review an NDIN for any other dietary ingredient on the grounds that doing so would prove "unduly burdensome," and, again, AHPA sees no reason to grant FDA the ability to set such a precedent for CBD or other hemp ingredients.

AHPA notes that current provisions of the FD&CA applicable to dietary supplements already provide FDA with authority to initiate enforcement action when the agency finds that an ingredient does not have an established history of safe use or other evidence demonstrating safety under the recommended or suggested conditions of use. Such authority and action are

demonstrated, for example, in FDA's August 23, 2017, warning letter to 1ViZN LLC[7] regarding a bitter orange extract product containing p-synephrine at a level that was considered to adulterate the product in the absence of such documentation. This letter advised that the agency considered the bitter orange product to be adulterated given that a notification was not submitted for the presence of p-synephrine at concentrations exceeding that naturally occurring in bitter orange (*Citrus aurantium*). FDA had authority to take this action, even in the absence of having authority to predetermine what would constitute a safe level for the ingredient in question.

Additionally, AHPA would object to use of the Interim Final Rule (IFR) process to establish any such daily serving limit for CBD-containing dietary supplement products. AHPA strongly believes that the public, members of the regulated industry, and other stakeholders should have the opportunity to submit data and provide input on any proposed daily serving limits in advance of their taking effect. Because the IFR process provides for only post-promulgation comment, industry members would need to comply with requirements of which they have had no advance notice and on which they provided no input. Accordingly, the IFR process appears ill-suited to promulgating prospective requirements such as these.

AHPA requests that the provision creating FDA authority for establishment of a CBD daily serving limit be removed from the CAOA proposal.

Mandatory requirement for all cannabidiol-containing supplements to be subject to NDINs [21 U.S.C. § 342 (Adulteration), 21 U.S.C. § 350b(a)(1) (New dietary ingredients)]
The CAOA contains proposed modifications that would deem all CBD-containing dietary supplements to be adulterated unless they have been the subject of an NDIN under the safety standard of "does not present a significant or unreasonable risk of illness or injury." Such a provision appears to prohibit CBD-containing supplements from being marketed under the food supply option at 21 U.S.C. § 350b(a)(1), which recognizes the lawfulness of new dietary ingredients already present in the food supply in the same chemical form (e.g., ingredients already in the food supply that qualify as "generally recognized as safe" or GRAS), and meeting the safety standard of "reasonable certainty of no harm under the intended use condition." AHPA sees no reason why federal law should treat CBD-containing dietary supplements any differently than any other dietary ingredients for purposes of the NDIN requirements.

Such a limitation could have the effect of restricting hemp-derived ingredients that are already recognized as GRAS from being utilized in a dietary supplement product without the additional

[7] Accessible at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/1vizn-llc-522724-08232017

submittal of the NDIN. For example, hemp seed oil is recognized as a GRAS food ingredient[8] but contains trace levels of CBD. The proposed restriction to the NDIN process implies that a marketer of a hemp seed oil dietary supplement in capsule form would have to submit an NDIN because of the trace presence of CBD in the hemp seed oil, despite the FDA-acknowledged GRAS status of the ingredient.

Additionally, AHPA is not aware of any data indicating that dietary ingredients that have been self-affirmed as GRAS, already exist in the food supply, and are used in dietary supplements pose a greater public health risk than those that have been evaluated via the NDIN process. GRAS assessments also require the public availability of safety documentation, which is not a requirement of the NDIN process, and arguably provides a greater assurance of safety.

AHPA requests that the limitation for using only the NDIN process for CBD-containing ingredients be removed from the CAOA proposal, allowing these ingredients to be evaluated using the same processes available to all other dietary ingredients.

FDA authority to establish labeling and packaging requirements specific to CBD-containing dietary supplements [21 U.S.C. § 342 (Adulteration)]

The CAOA discussion draft proposes provisions under which FDA would consider a CBD-containing product adulterated if it does not conform to packaging and labeling requirements established by FDA by regulation. AHPA supports FDA's authority to establish labeling and packaging requirements specific to dietary supplement products containing any specific ingredient that warrants such individualized requirements, including CBD, through notice and comment rulemaking. AHPA has expressed support for FDA to establish such authority in its July 2019 public comments provided to FDA's docket entitled "Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds." In those comments, AHPA noted that, in exercising its regulatory oversight over hemp products, FDA could impose requirements to disclose material information regarding their safe use in product labeling.

As noted previously, AHPA would object to using the IFR process to implement such authority and requests that the draft provision be amended to reflect that FDA may establish any such requirements only through standard notice and comment rulemaking.

Additional prohibited act for products labeled as dietary supplements but not meeting the definition of such products [21 U.S.C. § 331 (Prohibited Acts)]

The CAOA discussion draft contains a proposal to make it a prohibited act to market a product labeled as a dietary supplement that the agency determines does not meet the definition of

[8] GRAS Notice No. GRN 000778, accessible at https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=778

"dietary supplement." As proposed in the CAOA, this provision is not specific to hemp-derived CBD and would apply to all products labeled as dietary supplements. AHPA believes that FDA already has statutory authorities that the agency could use to enforce against such products.

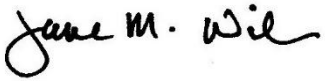
AHPA requests that this provision be removed from the CAOA discussion draft as representing a broad regulatory change that has enforcement implications far beyond the creation of a regulatory framework for hemp-derived CBD. AHPA believes that FDA already has statutory authorities that the agency could use to enforce against such products; if new authority is needed by the agency, it should be proposed in a legislative vehicle that is more likely to be reviewed and commented upon by the full dietary supplement industry.

Concluding remarks

We are nearing the three-year anniversary of the enactment of the 2018 Farm Bill, which reflected the decision by the U.S. Congress to support farmers and consumers by establishing a lawful process for production of hemp, including CBD and the other cannabinoids in hemp. Since that time, FDA has relied on an exclusionary provision to keep dietary supplements and foods that contain any amount of CBD in a regulatory gray zone, even though the agency already has authority to create a lawful framework for marketing such products. While AHPA has expressed support for other legislative efforts to create a regulatory pathway for these products, and AHPA appreciates the inclusion of this issue within the scope of the CAOA, our comments reflect the improvements we feel are necessary for this proposal to ensure consumers have access to safe dietary supplements, while avoiding unnecessary regulatory burdens on hemp product marketers.

AHPA greatly appreciates the opportunity to present comments during consideration of this important legislative proposal. We welcome any questions from the Sponsoring Offices that may arise from AHPA's comments.

Respectfully submitted,



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