October 8, 2019 **NEEDED HEMP/CBD POLICY CHANGES**

Dear Senators and Representatives:

On behalf of four of the major trade associations representing dietary supplement and natural products industries, we are writing to urge that you work to enact this year a statutory change and appropriate the resources necessary to provide timely legal clarity and consumer protections for the fast growing cannabidiol (CBD) marketplace. These actions are urgent given the strong consumer interest in CBD, the growth in products and sales, and the need for clarity among consumers, retailers, and manufacturers about the legal status of these products. A regulated and high quality CBD marketplace is also critical for our U.S. farmers as over 85 % of U.S. hemp production in 2019 is expected to be processed for CBD and hemp extract products. Legislative confirmation of CBD's legal status is crucial to hemp farmers and those considering a transition to hemp farming.

The 2018 Farm Bill took the historic step of legalizing the cultivation of hemp and the sale of the hemp plant and any of its parts and derivatives (including cannabinoids) that contain no more than 0.3% of the psychoactive compound tetrahydrocannabinol (THC). That statute explicitly maintained the Food and Drug Administration's (FDA's) authority over all hemp-derived products in categories otherwise regulated by the agency (e.g., conventional foods, dietary supplements, cosmetics, drugs), and FDA has repeatedly stated that dietary supplements and conventional foods containing hemp-derived CBD cannot be sold legally based on its interpretations of existing and generally applicable provisions of law.

While FDA has been working to craft its policy on hemp-derived products, in July 2019 testimony before the Senate Agriculture Committee, the agency stated that it could take three to five years for even an expedited rule-making process to establish a legal regulatory pathway for use of CBD in dietary supplements and conventional foods. Given the rapidly growing marketplace of products, it is crucial that Congress take quick action to clarify the legal status of hemp-derived CBD dietary supplements. At the same time, it is equally essential for FDA to have the resources it needs to protect the public from unsafe CBD products.

We urge you to pass legislation to clarify that CBD derived from the hemp plant is a lawful dietary ingredient if the dietary supplement containing the CBD meets established product safety and quality criteria. This would require a limited waiver of § 201(ff)(3)(B) of the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 321(ff)(3)(B), which governs articles used in both drugs and dietary supplements. To be subject to this limited waiver, CBD would have to be derived from hemp as defined by the 2018 Farm Bill, and any dietary supplement containing hemp-derived CBD must fully comply with applicable requirements for new dietary ingredients under the FDCA. Importantly, these products would also be required to fully comply with *all*

other provisions of the FDCA and FDA's implementing regulations applicable to dietary supplements, including those requiring accurate product labeling and good manufacturing practices as well as the prohibition against making any drug claims.

We are very appreciative that both the House and Senate FY 2020 Agriculture and Related Agencies Appropriations bills and reports have addressed the issue of hemp-derived CBD and provide much needed additional resources. This is an important reflection of the high degree of Congressional and public interest. The Senate bill specifically provides an additional $2 million for FDA's CBD work.

We urge Congress to go even further to include substantial new resources to enable effective FDA oversight of this fast-growing category, including funding for efficient and timely review of new dietary ingredient notifications and enforcement of existing laws governing the safety, manufacturing, and labeling of dietary supplements containing CBD. We urge that you work with FDA to determine a level of funding adequate to assure effective regulation of the CBD marketplace that does not detract from other agency enforcement priorities.

In sum, we urge you to provide FDA statutory authority and additional resources with explanatory report language to regulate CBD products as dietary supplements without the need for a multi-year rulemaking process. This is the best, most efficient, and most timely way to both set a clear regulatory framework for the marketplace and better assure consumer protection. While we can appreciate the FDA's deliberative interest in making sure that consumers have access to safe CBD products, we are concerned that continuing to leave the marketplace without clarity and adequate oversight for an extended period of years will both endanger consumers and the bright future of the hemp-derived products they seek. Since it appears FDA is unlikely to provide a timely and effective resolution to this challenge, Congress must act.

Thank you for your interest in and attention to this important and timely health issue. We stand ready and willing to continue to work with you and your staff as you craft policy in this area.

Sincerely,

Michael McGuffin
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American Herbal Products Association

Steve Mister
President & CEO
Council for Responsible Nutrition

Scott Melville
President & CEO
Consumer Healthcare Products Association

Loren Israelsen
President
United Natural Products Alliance

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal and botanical products industry. AHPA is comprised of more than 300 domestic and foreign companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal products, including foods, dietary supplements, cosmetics, and non-prescription drugs. Founded in 1982, AHPA's mission is to promote the responsible commerce of herbal products. Website: www.ahpa.org.

The Consumer Healthcare Products Association (CHPA) is the 137-year-old trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. Every dollar spent by consumers on OTC medicines saves the U.S. healthcare system $6-$7, contributing a total of $102 billion in savings each year. CHPA is committed to promoting the increasingly vital role of over-the-counter medicines and dietary supplements in America's healthcare system through science, education, and advocacy. Visit www.chpa.org and www.KnowYourOTCs.org.

The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. 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, Facebook, and LinkedIn.

The United Natural Products Alliance (UNPA) is an international trade association representing many leading natural products, dietary supplement, functional food, scientific and technology and related service companies that share a commitment to provide consumers with natural health products of superior quality, benefit and reliability. Founded in Utah in 1992, UNPA was instrumental in the passage of the 1994 Dietary Supplement Health and Education Act (DSHEA) and continues to take a leadership position in legislative and regulatory issues and industry best practices. Visit www.unpa.com.