January 8, 2019

Scott Gottlieb, M.D.
Commissioner of Food & Drugs
Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
Via email: CommissionerFDA@fda.hhs.gov

Dear Dr. Gottlieb:

On behalf of the American Herbal Products Association (AHPA), the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), and the United Natural Products Alliance (UNPA), we are writing to officially request a meeting with you and others at FDA regarding the pursuit of a lawful pathway to market for *products that contain cannabidiol (CBD) derived from hemp as lawful dietary supplements or foods.* Collectively, our associations represent a significant portion of the dietary supplement marketplace and many food and food ingredient producers as well.

First, we want to thank you for issuing the statement on December 20th, contemporaneous with the signing of the 2018 Farm Bill, clarifying the agency's authority and perspective on the regulation of products containing cannabis and cannabis-derived compounds. That legislation amended the definition of "marijuana" in Schedule I of the Controlled Substances Act to exclude the hemp plant and any of its parts and derivatives (including cannabinoids) that do not contain more than 0.3% tetrahydrocannabinol (THC), thus removing hemp and its constituents such as CBD from Drug Enforcement Administration control. However, your statement reiterates FDA's view that other legal obstacles to the lawful sale of certain CBD-containing products still remain. Our members appreciate FDA's initiative to make its viewpoint clear to the industry and to provide retailers and consumers with the explanation for the agency's position.

While we do not read the Federal Food, Drug, and Cosmetic Act as necessarily prohibiting the presence of any amount of CBD in any dietary supplement or food, we note that FDA has the ability to recognize products that contain CBD as lawful dietary supplements and foods pursuant to 21 U.S.C. §§ 321(ff)(3)(B) and 331(ll). Several alternatives are at FDA's disposal, including that the agency could exercise its discretion to exempt by regulation CBD from these provisions, as

provided for in the final clause of § 321(ff)(3)(B) and in § 331(ll)(2), and as alluded to in your December 20 statement. [1]

We further believe that exploring a legal path to market for dietary supplement and food products that contain CBD is consistent with the strong public health goals of the agency. Recognizing products that contain CBD as lawful foods or dietary supplements would allow the agency to impose a reasonable regulatory framework around the processing, manufacturing and marketing of CBD products not intended for use as drugs. Such recognition would permit the agency to enforce existing regulations regarding registration of manufacturing facilities; observance of GMP regulations; supply chain security; compliance with food additive and new dietary ingredients provisions for foods and dietary supplements, respectively and as relevant; mandatory serious adverse event reporting (in the case of dietary supplements); compliance with FSMA safety obligations (for food and dietary ingredients); notification to FDA of structure/function claims made for the products; and the full range of regulatory obligations imposed on food and dietary supplements by the FDCA. Conversely, if FDA fails to act, consumer interest in CBD will continue to grow along with a thriving—albeit potentially unlawful—array of CBD and hemp products.

Therefore, the above listed trade associations request the opportunity to meet as soon as possible with your office, and other relevant parties within FDA (e.g., the Office of Dietary Supplement Programs, CFSAN; Office of Compliance, CDER; Chief Counsel's Office; Office of Policy, Planning, Legislation & Analysis). We respectfully ask for at least one hour for this meeting to engage in a discussion of the options available to FDA to evaluate its position with respect to hemp and its cannabinoids. We believe the burgeoning consumer interest in hemp and its non-THC constituents demonstrates that swift and decisive action will be necessary to avoid an unregulated marketplace for these products. We commit our associations to collaborating with FDA to find a solution that permits a lawful pathway to market for these products.

[1] In particular, you noted as follows: "In addition, pathways remain available for the FDA to consider whether there are circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement. Although such products are generally prohibited to be introduced in interstate commerce, the FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement. We are taking new steps to evaluate whether we should pursue such a process. However, the FDA would only consider doing so if the agency were able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients."

Please have your staff respond to Jane Wilson at AHPA at jwilson@ahpa.org or (734) 476-9690, with some suggestions for when we might meet with you. Thank you for your prompt consideration.

Yours truly,

Michael McGuffin
President
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

cc: Steven Tave, Director, FDA Office of Dietary Supplement Programs, Steven.Tave@fda.hhs.gov

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 350 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 138-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 empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products. Visit www.chpa.org.

The **Council for Responsible Nutrition** (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 170+ 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 and LinkedIn.

The **United Natural Products Alliance** (UNPA) is an international trade association representing more than 100 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.