NATURAL PRODUCTS ASSOCIATION

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Testimony of Kyle Turk

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The Natural Products Association (NPA) is the leading and largest trade association representing the entire natural products industry. We advocate for our members who supply, manufacture, and sell natural ingredients or finished products for consumers. NPA is the voice of responsible industry stakeholders before federal, state and local governments. Founded in 1936, NPA represents approximately 650 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers, and distributors of natural products including foods, dietary supplements and health/beauty aids. As the leading trade association for the natural products industry, we have spearheaded the charge to include a cannabidiol (CBD) food pathway to market, however, there has not been any regulatory guidance from the United States Food and Drug Administration (FDA).

Background

On March 1, 2019, the FDA submitted a federal register notice involving cannabidiol for stakeholder notice and comment. The FDA provided interested persons with the opportunity to submit comments about the World Health Organization (WHO) recommendations to impose international manufacturing and distributing restrictions, under international treaties on certain substances. The Comments received were considered in preparing the United States' position on these proposals for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria. As a party to the 1971 Convention on Psychotropic Substances, whenever the CND proposes to add, transfer, or remove a drug from one of the schedules, the Secretary of State must transmit notification of this process to the Secretary of Health and Human Services (Secretary of HHS) and allow for public notice and comment. Regarding CBD preparations, WHO and its Expert Committee on Drug Dependence (ECDD) prepared a health hazard evaluation.[1] Cannabidiol while found in cannabis and cannabis resin, is not found to have the same psychoactive properties and results in no potential for abuse and potential to produce dependence.

[1] World Health Organization. (2017). Cannabidiol (CBD) Pre-Review Report Agenda Item 5.2. Expert Committee on Drug Dependence. Thirty-ninth Meeting. Geneva, 6-19 November 2017.

FDA contains a page on their website titled "FDA and Marijuana," where they clearly state that "FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201 (ff)(3)(B)(i) and (ii) of the Federal Food, Drug and Cosmetic Act (FD&C Act, respectively. Under those provisions, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act. Moreover, the page goes on to add further clarity that "[t]here is an exception to section 201 ff)(3)(B)(i) and (ii) if the substance was 'marketed as' a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable." However, based upon available evidence, FDA has concluded that this is not the case for THC or CBD. NPA is also aware of the warning letters for disease claims that FDA has issued to companies marketing CBD as a dietary supplement.

Despite, the FDA's actions and message, the market for CBD products in the United States is surging. According to a report issued by New Frontier Data, the United States CBD industry grew by nearly 40% in 2017, reaching $367 million in annual sales across hemp-derived and marijuana-derived markets. At the present the only federal approved CBD product is Epidolex, a pharmaceutical product manufactured by GW Pharma and approved by the FDA in 2018.

State of Regulatory Status

NPA applauds the efforts of the sponsors and the committee to address this issue. The time for enforcement of CBD is long overdue. Across the country we are seeing state after state recognize the gaps left by the FDA and begin to develop their own regulatory standards. While it is of our opinion that the best approach is for one uniform national standard. We understand the FDA has yet to take responsibility for this public health issue and establish a regulatory framework for manufacturers that would include establishing a safe daily level of consumption, inspecting facilities for manufacturing practices, and testing products for impurities such as high dosages of tetrahydrocannabinol (THC), pesticides and heavy metals.

In the past three years, over 3,000 CBD products have come to market without a consistent approach to regulation or any plan on how consumer access will be balanced with consumer safety by our public health officials at the Food and Drug Administration. NPA commissioned a poll that found seven in ten Americans believe the FDA is overdue to establish safety standards for the CBD products in the marketplace. To make matters worse, 41% wrongly assumed the FDA had already developed these safety standards.

Having the Food and Drug Administration establish a safe level of consumption for CBD products is the best way to move forward with this promising new product while protecting consumers.

CBD was first marketed as an active pharmaceutical ingredient (API), which creates some legal hurdles in marketing it as a dietary supplement or conventional food. The industry needs to be provided with the guidelines that they need and consumers with the assurance that deserve which means that what they are consuming is safe and is manufactured to quality standards. FDA has previously provided a path to market as dietary supplements/foods for natural products that contain an API by establishing a daily exposure level similar to what they did with monacolin K, the same ingredient that is in the prescription cholesterol-lowering drug lovastatin[2], which is found in Red Yeast Rice.

While CBD was technically a federally "scheduled" substance before the passage of the 2018 Farm Bill in December, sales of CBD products continued to rise to their current presence on the market which is well over 3,000 CBD products. When 2018 Farm Act was passed, which eliminated hemp from the definition of marijuana under the Controlled Substances Act- there was a significant and immediate increase in the production and sales of CBD products despite the fact that the Agency has continued to state that "[they have]concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the Federal Food, Drug, and Cosmetic Act."[3]

Despite this, the warning letters FDA has issued to companies marketing CBD as a dietary supplement, largely focus on claims. The Food and Drug Administration has enforcement authority over labeling requirements. Two well-recognized types of claims are health claims and structure function claims. Health claims describe the relationship between foods and dietary supplements and reduced risk of a disease or health-related condition. These claims are subject to premarket review and authorization by FDA. Structure Function claims describe the role of a nutrient or dietary ingredient intend to effect on the normal structure or function of the human body, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain the structure or function of the body or system of the body. The FDA requires manufacturers must have substantiation that such claims are truthful and not misleading and must provide FDA with notice of their intent to include the claims with the language for each claim, within 30 days of placing the product with the claim on the market. Following the most recent string of warning letters the FDA released a statement regarding their activity. FDA not only cited the ways in which recipients of warning letters have violated the Federal Food, Drug, and Cosmetic Act, but they also site the lack of scientific information supporting the safety of CBD in food and indicated that they cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in humans or animal food. As outlined in the some of the warning letters issued by the FDA, violations included marketing CBD products as a dietary supplement since these products do not meet the

[2] Red Yeast Rice, National Center for Complementary and Integrative Health https://www.nccih.nih.gov/health/red-yeast-rice

[3] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd

definition of a dietary supplement. FDA Principle Deputy Commissioner Amy Abernethy, M.D., Ph.D. even went as far to say "We remain concerned that some people wrongly think that the myriad of CBD products on the market, many of which are illegal, have been evaluated by the FDA and determined to be safe."

Because the FDA has not made the determination that CBD is generally recognized as safe, we at NPA have long advocated for FDA to test CBD products for cannabinoid content, heavy metals, pesticides, and THC content. Currently, through the United States Department of Agriculture, there are 37 hemp analytical testing laboratories. Through these testing facilities, any laboratory testing hemp for THC must be registered with the Drug Enforcement Agency. Unfortunately, the combination of the high volume of hemp produced and the lack of facilities has led to industry-wide concerns due to the relatively low capacity for testing.

This was the primary reason for our proposal to establish a national testing center and corporate stewardship program for manufacturers of CBD products at the National Center for Natural Products Research at the University of Mississippi. This program would provide an independent verification program for product analysis. The program would randomly select 1,000 products per year based upon their attestations that they contain hemp/CBD. These products would be tested using verified standards for their content of impurities (e.g., pesticides, etc.), THC, CBD and other cannabinoids. The data generated from this program would be shared with the FDA and published in a public-facing database for anyone to access.

In a recent FOIA request to the Agency, NPA found that the FDA only tested four facilities and three products for CBD in 2018 – for the entire calendar year. When one considers the more than 3,000 products on the market, a quantity that grows daily, we believe that these testing figures are unacceptable for a federal agency whose mission is to protect the public health. While we appreciate the sponsor's intent for the State to establish minimum testing requirements, it is our belief that this needs to be executed by the federal agency who is responsible for ensuring safe products are getting to market. Though the overall market situation for CBD-containing products is fraught with problems in terms of quality and consistency, responsible companies would welcome a federal avenue to be recognized for compliance. Some of these companies even expressed a strong desire for clear guidance during the FDA's May 31, 2019 hearing on CBD.

Finally, while we appreciate the sponsor's desire to protect young consumers from controlled substances that present an unreasonable risk to their health, we must caution the characterization of a dietary substance or supplement in the same light as a controlled substance. There are well-established reasons, and data to support the protection of young consumers (under the age of 21) from substances such as alcohol or tobacco due to their known addictive qualities. That said, a dietary supplements are intended to supplement the diet, to augment one's health. Cannabidiol does not have any addictive qualities, and when manufactured appropriately, does not contain THC above 0.3% (per federal regulations). We strongly encourage the sponsor to consider amending the bill's language to reflect that consumers under the age of 18 (or minors) should not purchase supplements containing CBD without a parent or guardian, rather than under the age of 21, as the bill is currently written. Please consider our proposal for testing through our National Testing Program, or through current Good Manufacturing Practice (cGMP) inspections by the

Agency, to address THC content. We urge the sponsor to avoid unfairly characterizing supplements in the same class or category as a controlled substance.

NPA and our member companies are concerned that without a clear federal regulatory pathway in place, tainted products will continue to enter the marketplace, leaving consumers susceptible to harm and discouraging legitimate companies from engaging in interstate commerce. Clear federal guidelines from the nation's public health agency awards compliant companies with the regulatory clarity they deserve when operating in interstate commerce. One uniform national standard is the most efficient way to move forward with this promising new product while protecting consumers. Thank you again for allowing us the opportunity to present the risks involved when our federal regulatory agency does not regulate CBD.