NATURAL PRODUCTS ASSOCIATION

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October 7, 2020

DEA Federal Register Representative
Drug Enforcement Administration
8701 Morrissette Drive, Springfield VA 22152

RE: RIN 1117-AB53 Docket NO. DEA-500

Dear DEA Federal Register Representative

Background:

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 750 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 cannabidiol (CBD) food pathway to market, however, there has not been any regulatory guidance from the United States Food and Drug Administration (FDA).

State of Regulatory Status:

The Agriculture Improvement Act of 2018, provided a new statutory definition of "hemp" and amended the definition of marijuana under 21 U.S.C. 802(16) and the listing of tetrahydrocannabinol under 21 U.S.C. 812(c). This amends the regulatory controls over marijuana, tetrahydrocannabinol, and other marijuana-related constituents in the Controlled Substances Act (CSA).

The proposed rulemaking would make four changes to the DEA's existing regulations:

1. It would add language to 21 CFR 1308.11(d)(31) by adding language stating that the definition of "Tetrahydrocannabinols" does not include "any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C 1639 o."
2. It removes from control in schedule V under 21 CFR 1308.15(f) a "drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinol."
3. It also removes the import and export controls described in 21 CFR 1312.30(b) over those same substances.

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4. It modifies 21 CFR 1308.11(d)(58) by stating that the definition of "Marihuana Extract" is limited to extracts "containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight basis."

We do not have any concerns with the first three changes to the DEA's existing regulations. The proposed changes would likely encourage the hemp and cannabidiol industries by removing cumbersome regulations that would have otherwise made it difficult for companies in those industries to maintain normal operations. The first proposed change removed hemp from the definition of tetrahydrocannabinol which supports that industry. This would make an immediate impact upon hemp farmers and remove unnecessary burdens to selling their crops. The second proposed change would remove from drug products that were derived from cannabis with no more than 0.1% w/w residual THC from control in schedule 1. This would serve to increase access to medications that are derived from cannabis and would immediately provide a positive impact on those patient populations that rely on those medications. The third proposed change removes import and export controls over hemp products which would positively impact the hemp and CBD industries, as well as the American economy.

While the belief of the Drug Enforcement Agency (DEA) that this final rule "merely conforms DEA's regulation to the statutory amendments to the CSA that have already taken effect…" and "there are no additional costs resulting from these regulatory changes…" we believe that the fourth proposed change in this interim final rule has devastating implications for the hemp and cannabidiol industry.

Hemp Extracts:

To date, 46 states have legalized hemp farming and over 510,000 acres of hemp were licensed across 34 states. This represents a 455% increase over 2018 licensed acreage. Additionally, according to the United States Department of Agriculture, most states require background checks for producers and require producers to provide Global Positioning System location information on their hemp fields and submit to audits or spot checks of the crop.

The Agriculture Improvement Act of 2018 (2018 Farm Bill) legalized hemp by removing the plants, its derivatives, extracts, and cannabinoids from the definition of marijuana under the Federal Controlled Substances Act. According to the DEA, the proposed final rule "merely conforms DEA's regulations to the statutory amendments to the Controlled Substance Act (CSA) that have already taken effect, and it does not add additional requirements to the regulations." Unfortunately, the 2018 Farm Bill failed to address the manufacturing processes of hemp, as did the United States Department of Agriculture's interim final rule, 84 FR 58522, which regulates the cultivation of hemp. This is a critical omission, which as occurred twice, because the proposed interim final rule states *"a cannabis derivative, extract, or product that exceeds the 0.3% D9-THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less D9-THC on a dry weight basis."*
To extract CBD or other cannabinoids from federally-compliant hemp, the hemp must first go through an extraction process which often causes a temporary increase in the concentration of Delta-9 THC even though the hemp contained less than 0.3 percent or less delta-9 THC on a dry weight basis before the extraction process. Therefore, the

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the byproduct that is created in an intermediate step will be considered to be a Schedule I substance according to the DEA, even though this by-product would not be sold to consumers in that state. As its name indicates, the by-product from the intermediate step would always be diluted to the required concentration in the finished product before it was sold to a consumer. That said, if the facility were to be inspected and a sample was collected from the intermediate step in the extraction process, the firm would be found to have a schedule I controlled substance. This makes it virtually impossible to ensure the hemp from which CBD is extracted will not exceed the 0.3 percent limit. Thus, putting hemp processors in a perpetually non-compliant status with the DEA.

The FDA ultimately has jurisdiction over CBD, therefore, the administration needs to clarify how this will implicate the food and beverage industry. Since current good manufacturing practices (cGMPs) have set for specifications for allowable levels of THC that have been adopted by the industry, we are concerned that the administration has elected to focus on the incoming raw material when the focus should be on what is done with the residual THC. If manufacturers do not have a license from the administration, then the firm should have records of destruction for the residuals. We are concerned as this issue is not represented in the final rule.

National Testing Standards:

Despite the FDA's determination that it is unlawful under the Federal Food Drug and Cosmetic Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived, CBD continues to be widely marketed and sold in both food and dietary supplements. The FDA's latest report, sent to Congress on July 8, evaluates the CBD marketplace and underscores a growing need for consistent regulation. In its study, the FDA tested 147 products for 11 different cannabinoids, including CBD and total tetrahydrocannabinol levels. Of the 102 products that indicate a specific amount of CBD, the FDA found:

- 18 contained less than 80% of the amount of CBD indicated.
- 45% contained within 20% of the amount of CBD indicated.
- 37% contained more than 120% of the amount of CBD indicated.
- Of the 147 products, nearly half contained levels of THC above the limit of quantitation, which is 3.1 mg per serving.

NPA and our member companies found it concerning that neither the FDA nor DEA had not taken any action on the products they found to exceed the limit of THC. This lack of consistency begs the question of whether either the FDA or DEA found these products to be a problem and if not why?

This is why we have proposed to establish a national testing center and corporate stewardship program for manufacturers at the National Center for Natural Products Research. This program would provide an independent verification program for product analysis. These products would be tested using known standards for their content of THC, CBD, and other cannabinoids. The data generated from this program would be provided to the FDA and DEA and published in a

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public-facing database that anyone could access. These standards would also highlight the records necessary to prove that material is within compliance with federal law, whether it has been reworked or destroyed. This would provide the consistency the industry needs which is not provided in the current proposal.

Conclusion:

According to Grand View Research, China is the largest exporter of raw and processed hemp products in the United States and to the world. This is because China has a well-established supply chain and highly developed facilities that have led to highly competitive cost-effective products. This rule would put American hemp farmers at a disadvantage as hemp processing would be illegal in most cases as the extraction will likely yield a level of delta-9 THC that is above the 0.3% limit, albeit transiently. While other industries are looking to move away from a reliance on China, this proposed rule hurts American businesses. Rules like this one proposed today further create an environment where our farmers, manufacturers, processors, and small businesses are at a competitive disadvantage to the Chinese.

Should this interim final rule materialize, it would jeopardize the hemp and CBD industries. As written, the interim final rule would indicate to the industry since the rule criminalizes processors who have been subjected to criminal background checks, that they are handling a schedule I controlled substance during the manufacturing process, despite the fact the finished product contains no more than 0.3 percent Delta-9 THC. By submitting criminal background checks and operating through appropriate commerce channels within their respective states, these manufacturers have established that are willing and able to work within the confines of the law and produce compliant hemp products. Both the FDA and DEA must resolve the current disconnect providing the industry with the much-needed clarity they rely upon to provide consumers with consistent and high-quality products.

Thank you,

Daniel Fabricant, Ph.D.
President and CEO
Natural Products Association