



October 20, 2020

Mr. Scott A. Brinks
Diversion Control Division
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Mr. Brinks:

We thank you for the opportunity to provide our views on the Drug Enforcement Agency's (DEA) interim final rule (IFR) titled Implementation of the Agriculture Improvement Act of 2018.

The National Industrial Hemp Council (NIHC) is a global advocate for North American industrial hemp, promoting the sustainable long-term growth and profitability of the industry. The NIHC's leadership is composed of leading international, federal, state, private industry, and government professionals throughout the hemp sector. The NIHC's membership includes farmers that grow hemp, suppliers of farm-related equipment to the hemp industry, cannabidiol (CBD) product manufacturers, hemp textile manufacturers, and others with an interest in the hemp industry.

NIHC believes that this IFR contains provisions which could be very helpful to establish a solid regulatory structure to allow for growth in commerce nationwide as well as on an international basis. Integrity in compliance is vitally important to ensure smooth marketing channels. But the language of the IFR has led to concern among some in the hemp industry regarding CBD which exceeds the allowable THC threshold only on a temporary basis during processing.

We were pleased to see comments in the news media by DEA staff confirming that enforcement actions against hemp processors are not the agency's highest priority. Enforcing these regulations during the processing stage for CBD which is never entered into commerce for human consumption would be a wasteful use of DEA resources.

We would appreciate your consideration of our concerns and your diligence to ensure that regulations do not inhibit the burgeoning hemp industry. We were heartened to learn of the efforts of DEA staff to conduct public education outreach with the law enforcement community

following passage of the 2018 farm bill to help them understand the difference between marijuana and hemp which has been a source of turmoil for interstate commerce. We strongly encourage you to do something similar when this rule becomes final.

We also strongly encourage you to remain cognizant that hemp is a legal commodity now and maintain a strong commitment to providing maximum flexibility to help the hemp industry comply with these regulations. You do not need to try to shut down or over burden the industry but rather focus on stopping illegal activity under the good name of hemp.

We noted with interest the letter from the National Center for Natural Products Research at the University of Mississippi to the U.S Food and Drug Administration (FDA) on August 19, 2020 in response to docket number FDA-2020-D-1079. As you're undoubtedly aware, this entity holds the sole license for cultivating research marijuana in the U.S. Their letter stated:

“...the difficulties we all face in the application of the strict limit of the single compound THC in a complex mixture to determine if that material is a DEA controlled substance, or not. The fact that common extraction procedures concentrate the constituents in intermediates prior to formulation of the final product must be addressed by DEA. A practical solution could be a new DEA registration category for ‘hemp processors’ that would require a registrant to handle concentrated hemp extract as a Schedule-I material during processing using approved diversion control and documentation procedures. Because the production process would begin with non-controlled raw materials and would result in a final product that meets the definition of hemp, this activity would comply to treaty requirements because no controlled substance would be manufactured for distribution.”

While NIHC believes that this might not be the only “practical solution” and is not prepared to recommend or endorse such a registration process we bring this up merely to strongly advocate that DEA keep at the top of mind that the hemp industry is struggling to grow among myriad challenges, many hemp processors are small businesses with limited capital, and the last thing that they need is burdensome and/or costly requirements while they are struggling to develop this market and take advantage of the promise that it holds. The large majority of hemp processors are doing the right thing and want to demonstrate to the public that they are producing a legal and safe product.

As you're fully aware, the requirement for DEA registration for testing labs was proposed through the USDA regulatory process which elicited strong concerns regarding the ability of labs to become registered and highlighted capacity concerns. While we appreciate that USDA currently has that issue placed on hold, labs do not yet have certainty and as labs have explored the potential need for compliance with the registration process, they have reported to us an acute concern with a lack of clear guidance from your DEA field agents. Instead of walking the CBD processors through the registration requirements and giving them a thorough understanding of what is required, DEA field agents have sent a copy of the federal regulations for the lab to read. DEA field agents are even less familiar with implementing DEA Schedule 1 requirements in a

production facility as compared to a laboratory. If testing labs are having difficulty and lacking clear guidance from your field agents what should processors expect?

In our comments to the U.S. Department of Agriculture (USDA) regarding their hemp regulatory process NIHC noted that we appreciate that their Interim Final Rule includes a “safe harbor” provision which specifies that hemp producers do not commit a negligent violation if they use reasonable efforts to grow hemp and the plant does not have a THC concentration of more than 0.5% on a dry weight basis. 7 C.F.R. § 990.29(c). <https://hempindustrial.com/the-national-industrial-hemp-council-calls-for-improvements-to-usdas-hemp-interim-rule/> We urge DEA to adopt a similarly lenient policy as it pertains to hemp processors who are endeavoring to produce legal and safe products.

DEA could also consider a policy of delegating enforcement authority to state agencies, similar to the USDA process. Furthermore, we believe a similar precedent exists with the three-tier system that is used to regulate alcohol distribution and gives states some flexibility. While we’re not prepared to suggest the details of such a regulatory scheme nor would we endorse one, we feel it’s important to note that this model exists and that the DEA might consider something similar to allow for state-based regulations of hemp processors.

We would also point out that the U.S. Food and Drug Administration (FDA) has regulatory authority over hemp CBD products and is currently in the process of finalizing a policy of enforcement discretion in relation to CBD, as directed by Congress. We would again urge DEA to follow the strong precedent of reasonable accommodations set by your sister agencies by adopting a similar policy of flexibility in regard to negligence or enforcement discretion or completely ceding jurisdiction to FDA during the processing stage as it is an integral step in creating consumable products from hemp. NIHC made very specific recommendations to FDA including parameters for quality and labeling to protect consumers. <https://hempindustrial.com/nihc-delivers-specific-recommendations-for-fda-to-regulate-cbd/> Those labeling provisions could be extended to the mid-process stage as needed. Any CBD in concentrated form during manufacturing processes should be labeled as not for consumption and never entered into commerce.

This should be sufficient, especially in light of how the DEA’s IFR correctly pointed to FDA’s vital role:

“The FDA also affirms its regulatory oversight over cannabis-derived compounds, such as CBD, whether or not these compounds are ‘classified as hemp under the 2018 Farm Bill.’ For these reasons, DEA considers any potential costs or benefits broadly related to changes in the markets for domestic hemp extracts due to their decontrol, including but not limited to the expansion in the number of producers, consumer products, and the impact on supply chains to be outside the scope of this analysis.”

Thus, if DEA attempts to insert itself unnecessarily into the processing stage it would be another cook in the kitchen that is not needed as hemp CBD is well regulated and controlled by other agencies.

In summary: NIHC represents federally legal hemp. We do not represent marijuana. We strongly support integrity in compliance with current laws. NIHC is actively leading efforts to shape federal policy and support market development for hemp. Beyond evolving current policy issues, our long-term focus remains intently on growing the recognition and acceptance of hemp as a mainstream commodity and hemp products as mainstream consumer products. We fiercely protect the brand of hemp as it is adopted by large mainstream iconic American companies. The industry does not need DEA to disrupt the market of well-meaning CBD processors. We do, however, appreciate the involvement of DEA in educating the industry, protecting consumers, and helping develop the market for this valuable agricultural commodity in its nascent stages of growth. Clarity from DEA is sorely needed to alleviate what has become a source of fear in the industry since its announcement.

We thank you for your consideration of our comments and we look forward to working with the agency on behalf of the millions of consumers across the country who use CBD products.

Sincerely,



Patrick Atagi
Board Chairman
National Industrial Hemp Council