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NCIA Policy Council
NCIA Scientific Advisory Committee
NCIA Hemp Committee

U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

COMMENTS BY THE NATIONAL CANNABIS INDUSTRY ASSOCIATION to the DRUG ENFORCEMENT ADMINISTRATION

"Implementation of the Agriculture Improvement Act of 2018"

RIN 1117-AB53
Docket No. DEA-500
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On August 21, 2020, the Drug Enforcement Administration (DEA) published to the Federal Register an Interim Final Rule (IFR) with request for public comments. Although the DEA's stated purpose of the IFR is to merely align DEA regulations with the statutory requirements created by the Agriculture Improvement Act of 2018 (AIA), the IFR is in direct conflict with hemp provisions in the AIA. The IFR also circumvents the rulemaking process as required by the Administrative Procedure Act (APA). The National Cannabis Industry Association (NCIA) and our nearly 2,000 members therefore request that this IFR be withdrawn.

At issue are the following representations made by DEA in the IFR:

> (1) *Pursuant to the AIA, unless specifically controlled elsewhere under the CSA, any material . . . that contains 0.3% or less of delta-9 THC on a dry weight basis—i.e., "hemp" as that term defined [sic] under the AIA—is not controlled. Conversely, any such material that contains greater than 0.3% of delta-9 THC on a dry weight basis remains controlled in schedule I.*
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> . . .
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> (2) *The AIA does not impact the control status of synthetically derived tetrahydrocannabinols . . . because the statutory definition of "hemp" is limited to materials that are derived from the plant Cannabis sativa L. For synthetically derived tetrahydrocannabinols, the concentration of Δ^9-THC is not a determining factor in*

whether the material is a controlled substance. All synthetically derived tetrahydrocannabinols remain schedule I controlled substances.

These statements within the IFR have already had a negative impact on the hemp industry, causing confusion and consternation among our members. We therefore submit these public comments to:

(A) demonstrate that this rulemaking is invalid under the APA because the DEA has gone beyond merely conforming its regulations to the AIA by instead creating new rules that require formal notice and comment;

(B) clarify that Congress explicitly limited DEA's jurisdiction to non-conforming hemp that exceeds 0.3% Delta-9 THC concentration on a dry weight basis where the producer was shown to have a culpable mental state greater than negligence;

(C) suggest definitions of "synthetic" and "natural" that are consistent with those definitions used by other federal agencies;

(D) recommend that the DEA leave it to the Food and Drug Administration (FDA) to regulate hemp-derived cannabinoids in the interest of public safety, given that the DEA itself has no authority to regulate products that have been de-scheduled; and

(E) clarify that in passing the AIA, Congress de-scheduled the interim products of hemp extraction, even if the biproducts temporarily exceeded the 0.3% Delta-9 THC threshold and amended the CSA accordingly.

A. Because the DEA's IFR goes beyond merely amending the agency's regulations to conform with the AIA, and attempts to re-write the AIA, the exceptions to the APA claimed within the IFR do not apply, and the rule is invalid.

Pursuant to the Administrative Procedure Act (APA), notice of rulemaking by any Federal agency must be published in the Federal Register and must be accompanied by an opportunity for the public to submit written comment by interested persons.[1] The DEA has failed to provide that statutorily required notice or follow such procedure.

It is true that, in limited circumstances, notice may not be required where the agency finds, for good cause, that the notice and public comment procedure is "impracticable, unnecessary, or contrary to the public interest."[2] The DEA claims that the statutory exception to the requirement of providing notice and comment pursuant to the APA applies here because the IFR "merely conforms DEA regulations to the statutory amendments to the CSA that have already taken effect, and it does not add additional requirements to the regulations," such that notice and public comment is unnecessary.[3]

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[1] 5 U.S.C. § 553(b)(c)

[2] 5 U.S.C. § 553(b)(B)

[3] IFR at page 51639

This view is mistaken because the IFR explicitly conflicts with provisions codified in federal law. For instance, the IFR further amends the defined terms "hemp," "marijuana," and "tetrahydrocannabinol" in ways unintended by, and in conflict with, Congress when they defined those terms in the AIA.

As a federal agency, DEA has no authority to create new law that is unauthorized by Congress.[4] DEA's authority here is limited to interpreting laws passed by Congress and creating regulations through notice and comment rulemaking. For instance, while the AIA legalized hemp by removing the hemp plant, extracts, and derivatives from the CSA's definition of marijuana, the published IFR attempts to criminalize all "work in progress" hemp (as defined in Section E below) in direct contradiction of the AIA. Thus, the IFR does more than merely incorporate the statutory amendments of the AIA into DEA's regulations. As a result, the IFR was published in violation of specific statutory requirements of the APA and should be retracted.

B. Congress removed all hemp and hemp-derived products with a Delta-9 THC concentration of less than 0.3% on a dry weight basis from the jurisdiction of DEA

As the law enforcement arm of the Department of Justice (DOJ) tasked with enforcing the controlled substances laws of the United States, DEA's jurisdiction over particular substances is limited to those scheduled pursuant to the CSA (and Federal Analogue Act). As DEA is well aware, all conforming hemp was removed from the CSA's purview following passage of the AIA. Indeed, the AIA has specific exemptions even for negligence whereby hemp and hemp-derived products may rise above 0.3% Delta-9 THC on a dry-weight basis.[5]

Under the AIA, hemp—which is expressly excepted from the definition of marijuana in Schedule I—includes "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing, harvested or processed, with a Delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."[6],[7]

This clear statutory definition unequivocally exempts all conforming hemp and hemp-derived products from any drug schedule within the CSA. Accordingly, the DEA has no jurisdiction to regulate any hemp growing, harvested or processed with less than 0.3% Delta-9 THC, nor any seeds, derivatives, extracts, cannabinoids, isomers, acids, salts, or salts of isomers if they have been obtained from that plant. In other words, all hemp-derived cannabinoids, extracts, cannabinoids, isomers, acids, salts, or salts of isomers are necessarily de-scheduled and outside DEA's jurisdiction if they conform to applicable state, tribal and USDA requirements set forth under the AIA.

[4] 5 U.S.C. § 551 et seq.
[5] 7 U.S.C. § 1639p (e)
[6] 21 U.S.C. § 802(16)(B)
[7] 7 U.S.C. § 1639o

C. There is no current definition of "natural" or "synthetic" in the Controlled Substances Act, and the DEA should clarify that the meaning of these terms in any CSA-related rulemaking and should do so in a manner consistent with existing federal law regarding these terms

Currently, there is no definition of "synthetic" or "natural" in the CSA, nor does the DEA propose one in the IFR. The DEA nevertheless asserts a proposed rule with respect to "synthetically derived tetrahydrocannabinols" in the IFR that is causing widespread confusion in the hemp industry.

Fortuitously, definitions of "natural" and "synthetic" do exist in regulations of the DEA's sister agencies, the USDA and FDA. In any rulemaking on this subject, the DEA should promulgate a definition of these terms consistent with the definitions used by the USDA and FDA.

Pursuant to 7 U.S.C. §6502(22), the term "synthetic" is defined as "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes." Furthermore, the USDA has published guidance on the definition of synthetic versus natural products and processes, which is consistent with similar FDA regulations on when Food Additives are defined as "naturally occurring."[8]

Accordingly, we ask that the DEA promulgate a legal definition of "synthetic" and/or "natural" specifically applicable to the CSA that aligns with the definitions found in other federal laws to alleviate confusion within the industry.

D. Even though the DEA lacks regulatory authority, we urge the FDA to begin effective public safety regulation on hemp-derived cannabinoids

As noted above, DEA has no role in the regulation of or enforcement against conforming hemp or hemp-derived compounds. However, because regulation is necessary for public safety and industry reliability and development, the FDA should begin promulgating public safety regulations for hemp-derived cannabinoids. NCIA therefore requests that DEA recognize the absence of its own authority to regulate on these subjects and, in light of its own lack of authority, NCIA reiterates prior requests that the FDA promulgate such regulations.

[8] NOP5033-1 USDA Agricultural Marketing Services "Guidance Decision Tree for Classification of Materials as Synthetic or Non-synthetic."

E. DEA lacks authority to regulate "work-in-progress" extracts derived from hemp, even those temporarily above 0.3% Delta-9 THC, because Congress approved of Delta-9 THC concentrations greater than 0.3% in "work-in-progress" extracts, and lawful processing of hemp unavoidably results in concentrations of Delta-9 THC that temporarily exceed this threshold during intermediate steps of the extraction process

Under the AIA, whether a harvested Cannabis sativa L plant is CSA-controlled marijuana or CSA-exempt conforming hemp is dependent on the dry weight percentage concentration of Delta-9 THC. This concentration does not remain steady at all times during the plant's life cycle, including during growth and extraction. During the extraction process, the calculated percentage of Delta-9 THC in the hemp being processed fluctuates as it is stripped of plant material. At certain intermediate steps prior to the final refinement of the desired extract, most of the weight of the hemp plant will have been removed, resulting in a Delta-9 THC concentration that temporarily rises above the 0.3% threshold, before the final refinement to a concentration below 0.3% can be completed. In most cases, this cannot be avoided, even in extremely low-Delta-9 THC strains of Cannabis sativa L grown as hemp. When plant material is removed, everything remaining becomes concentrated and may need to be remediated to comply (which, of course, ordinarily occurs through the completion of the very extraction process that is then in-process).

If DEA were to take the position that "work-in-progress" extracts that exceed the 0.3% threshold, even temporarily, are marijuana (and therefore subject to DEA authority and enforcement measures), legal hemp extraction would be functionally and legally impossible, which was clearly not Congress's intent in passing the AIA. Further, regulatory action would be costly, arbitrary and counterproductive, given the large number of processors that are properly registered, licensed, and making best efforts to comply with the complex state and federal regulatory scheme that currently governs the industry.

In light of the plain text of the AIA regarding "extracts" in the definition of hemp, Congress necessarily intended that "work-in-progress" extracts exceeding the 0.3% Delta-9 THC concentration limit which comply with tribal and state programs do not violate the regulations, since the creation of most extracts requires a process that results in a temporary Delta-9 THC concentration in excess of 0.3%. Any other interpretation of the AIA would be in direct tension with the statutory text and would outlaw most hemp extracts. Any such interpretation would criminalize an intermediate input because of its temporary chemical composition. This is particularly true because this process is occurring during a period in which the product is not even available for sale.

Put simply, the DEA cannot control substances such as hemp, and hemp-derived cannabinoids, that Congress expressly de-scheduled. For the foregoing reasons, the National Cannabis Industry Association objects to this rulemaking in its entirety and asks that DEA withdraw its notice.

Sincerely,

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