



October 20, 2020

Mr. Timothy J. Shea
Acting Administrator
United States Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

RE: RIN 1117-AB53/Docket No. DEA-500; Implementation of the Agriculture Improvement Act of 2018

Dear Acting Administrator Shea:

The Council on Governmental Relations (COGR) is an association of 190 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. COGR currently coordinates a working group consisting of approximately 25 members with diverse backgrounds from various institutions across the U.S. with substantial interest in conducting much-needed research about cannabis, including research about the efficacy, safety, and side effects of cannabis use, as well as the impact of cannabis on humans, animals and the environment.

COGR appreciates the opportunity to submit comments in response to the publication of the U.S. Drug Enforcement Agency (DEA) Interim Final Rule (IFR) on the Implementation of the Agriculture Improvement Act of 2018 (2018 Farm Bill). We commend the DEA for making clear in the IFR that unless specifically controlled elsewhere under the Controlled Substances Act (CSA), any material that was previously controlled as marijuana or marijuana extract and that contains 0.3% or less of Δ^9 -THC on a dry weight basis is now considered “hemp” and is no longer controlled under the CSA. We understand the DEA’s IFR to mean that researchers working with Cannabis sativa extracts that themselves contain no more than 0.3% Δ^9 -THC need not obtain a Schedule I registration and need not seek documentation about the THC content of the particular cannabis plant from which the extract was derived. The ability for researchers to import and export hemp, including hemp seeds and hemp derivatives that contain 0.3% or less of Δ^9 -THC, and to work with those substances without the need to obtain a Schedule I DEA registration will reduce burden, save time and costs, and will open the doors for our researchers to conduct important research more expeditiously.

Hemp Processing and Extraction

The IFR mentions that the definition of hemp “does not automatically exempt any product derived from a hemp plant, regardless of the Δ^9 -THC content of the derivative. To meet the definition of “hemp,” and thus qualify for the exemption from Schedule 1, the derivative must not exceed the 0.3% Δ^9 -THC limit.” COGR shares the U.S. Hemp Roundtable’s concern (see letter to DEA dated 9/15/20) that because the process of extracting low-THC derivatives like CBD from hemp may entail removing substances that themselves contain THC concentrations of higher than 0.3%, hemp processors – including researchers who may wish to extract low-THC derivatives like CBD from hemp to further their research – would need to obtain a Schedule I DEA registration to avoid potential exposure to criminal penalties. This would be contrary to the goal of easing regulatory burden for individuals and entities engaged in hemp production and processing solely for the purpose of producing low-THC products like CBD, including for research purposes.

We recommend that DEA provide guidance on how a non-registrant can comply with federal law during the processing of hemp.

Synthetically Derived Tetrahydrocannabinols

The IFR states that, while tetrahydrocannabinols contained in hemp are now excluded from Schedule I, “the AIA does not impact the control status of synthetically derived tetrahydrocannabinols (for Controlled Substance Code Number 7370) 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.”

We would appreciate clarification about the intended scope of the above language about the status of synthetically derived “tetrahydrocannabinols.” That is, please clarify whether that language applies only to synthetic cannabinoids that are psychoactive and known to have the highest abuse potential or whether it is meant to apply to all synthetically derived cannabinoids -- including synthetically-derived CBD -- that contain no more than 0.3% Δ^9 -THC. Specifically, we would appreciate clarification as to whether CBD derived from a source other than a *Cannabis sativa L.* plant is a “tetrahydrocannabinol” that DEA would consider a schedule I controlled substance. Clarification in this area is critical, because there is significant research interest in developing non-psychoactive cannabinoids from sources other than cannabis plants, but there is confusion about whether/how such substances are controlled, particularly in light of the Federal Analogue Act. We believe that, at least in those cases where non-cannabis-derived CBD is not intended for human consumption, it would not be a controlled substance analogue controlled as Schedule I. But we

would appreciate DEA's confirmation of this, particularly given the uncertainty about which substances DEA meant to reference in its statement in the IFR that "all synthetically derived tetrahydrocannabinols remain schedule I controlled substances."

Ultimately, COGR seeks clarification of which cannabinoids commonly used in scientific research are controlled and which are no longer controlled.

Thank you again for the opportunity to comment. We hope that the information provided herein is useful to DEA. If you have any questions regarding these comments, please contact Jackie Bendall, Director of Contracts and Grants Administration at jbendall@cogr.edu.

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streit". The signature is written in a cursive style with a large, looping "S" at the end.

Wendy D. Streit
President