Tab 6

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

January 16, 2018

Bryan A. Krumm, CNP
733 Monroe, NE
Albuquerque, New Mexico 87110

Dear Mr. Krumm:

This responds to your petition, dated May 22, 2017, asking the Drug Enforcement Administration (DEA) to initiate rule making proceedings pursuant to the Controlled Substances Act (CSA). Specifically you petitioned DEA to propose a rule, pursuant to 21 U.S.C 811(a), to remove marijuana from the CSA schedules. As you know, in August 2016, DEA denied your prior petition to remove marijuana from schedule I.

In response to your prior petition and a separate petition submitted by another group, DEA and the Department of Health and Human Services (HHS) conducted a scientific and medical evaluation and concluded that marijuana must remain in schedule I based on the statutory criteria. According to HHS, marijuana has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As stated in the 2016 Federal Register notices that contained the denials of those petitions (81 FR 53688 and 53767), after considering HHS's scientific and medical evaluation and scheduling recommendation for marijuana, along with all other relevant data, DEA concluded that there was no substantial evidence to remove marijuana from schedule I.

Your latest petition is based again in large part on your contention that marijuana has a currently accepted medical use in treatment in the United States.[1] However, the information you present in support of that contention fails on its face to meet the established five-part test for demonstrating that a substance has a currently accepted medical use in treatment in the United States. These criteria have been repeatedly set forth by the agency and upheld by the United States Court of Appeals. *See, e.g., Americans for Safe Access v. DEA*, 706 F.3d 438 (D.C. Cir. 2013). As indicated therein, to establish a currently accepted medical use in treatment in the United States for a drug that has not been approved for marketing by the Food and Drug Administration, a petitioner must, among other things, present adequate and well-controlled studies demonstrating the safety and efficacy of that drug. As to this point, your latest petition

[1] You also appear to be asking that marijuana be removed entirely from the schedules so that it can be regulated solely by the States, rather than the federal government. Since your desire to remove the federal government from any role in regulating marijuana as a controlled substance – and to transfer such role exclusively to the States – is not a basis for rescheduling under the CSA (and is incompatible with Congress's basic intentions under the Act), it may be rejected without further explanation. You also contend that marijuana does not have a high potential for abuse, yet you provide no support for this contention. Thus, this is merely an empty restatement of a contention that the agency previously rejected in response to your prior petition – which warrants no reevaluation by the agency.

adds nothing to your prior petition as you have pointed to no new studies that even purport to establish the safety and efficacy of marijuana. To the contrary, you have simply provided citations to new papers that consist only of reviews of other studies – none of which was designed to, or purports to, demonstrate the safety and efficacy of marijuana. Indeed, the papers to which you cite themselves acknowledge that they are preliminary in nature and would require additional study to draw any definitive conclusions about the safety or efficacy of marijuana.

When Congress enacted the scheduling provisions of the CSA set forth in 21 U.S.C. 811(a) through (c), it did not intend to require the two reviewing agencies (DEA and HHS) to perpetually conduct one eight-factor analysis after another for the same substance every time a prior petition to reschedule that substance was denied – and where a petitioner simply puts forth a cursory claim for rescheduling. While the CSA does require DEA to obtain a scientific and medical evaluation and scheduling recommendation from HHS before initiating proceedings to reschedule a substance, this does not mean DEA must refer every petition to HHS, especially where the petition, on its face, fails to meet the established criteria for rescheduling. It would be an extremely inefficient use of both agencies' resources to conduct such unending analyses based on a submission that plainly fails to materially alter the prior agencies' determination.

For the foregoing reasons, your petition, though accepted for filing, is denied.

Sincerely,

Robert W. Patterson
Acting Administrator