DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Chapter II

[Docket No. DEA–427]

Denial of Petition To Initiate Proceedings To Reschedule Marijuana

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Denial of petition to initiate proceedings to reschedule marijuana.

SUMMARY: By letter dated July 19, 2016 the Drug Enforcement Administration (DEA) denied a petition to initiate rulemaking proceedings to reschedule marijuana. Because the DEA believes that this matter is of particular interest to members of the public, the agency is publishing below the letter sent to the petitioner which denied the petition, along with the supporting documentation that was attached to the letter.

DATES: August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812

SUPPLEMENTARY INFORMATION:

July 19, 2016

Dear Mr. Krumm:

On December 17, 2009, you petitioned the Drug Enforcement Administration (DEA) to initiate rulemaking proceedings under the rescheduling provisions of the Controlled Substances Act (CSA). Specifically, you petitioned DEA to have marijuana removed from schedule I of the CSA and rescheduled in any schedule other than schedule I of the CSA.

You requested that DEA remove marijuana from schedule I based on your assertion that:

1. Marijuana has accepted medical use in the United States;

2. Studies have shown that smoked marijuana has proven safety and efficacy;

3. Marijuana is safe for use under medical supervision; and

4. Marijuana does not have the abuse potential for placement in schedule I

In accordance with the CSA scheduling provisions, after gathering the necessary data, DEA requested a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services (HHS). HHS concluded that marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision. Therefore, HHS recommended that marijuana remain in schedule I. The scientific and medical evaluation and scheduling recommendation that HHS submitted to DEA is attached hereto.

Based on the HHS evaluation and all other relevant data, DEA has concluded that there is no substantial evidence that marijuana should be removed from schedule I. A document prepared by DEA addressing these materials in detail also is attached hereto. In short, marijuana continues to meet the criteria for schedule I control under the CSA because:

(1) *Marijuana has a high potential for abuse.* The HHS evaluation and the additional data gathered by DEA show that marijuana has a high potential for abuse.

(2) *Marijuana has no currently accepted medical use in treatment in the United States.* Based on the established five-part test for making such determination, marijuana has no ''currently accepted medical use'' because: As detailed in the HHS evaluation, the drug's chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.

(3) *Marijuana lacks accepted safety for use under medical supervision.* At present, there are no U.S. Food and Drug Administration (FDA)-approved marijuana products, nor is marijuana under a New Drug Application (NDA) evaluation at the FDA for any indication. The HHS evaluation states that marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. At this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

The statutory mandate of 21 U.S.C. 812(b) is dispositive. Congress established only one schedule, schedule I, for drugs of abuse with ''no currently accepted medical use in treatment in the United States'' and ''lack of accepted safety for use under medical supervision.'' 21 U.S.C. 812(b).

Although the HHS evaluation and all other relevant data lead to the conclusion that marijuana must remain in schedule I, it should also be noted that, in view of United States obligations under international drug control treaties, marijuana cannot be placed in a schedule less restrictive than schedule II. This is explained in detail in the accompanying document titled ''Preliminary Note Regarding Treaty Considerations.''

Accordingly, and as set forth in detail in the accompanying HHS and DEA documents, there is no statutory basis under the CSA for DEA to grant your petition to initiate rulemaking proceedings to reschedule marijuana. Your petition is, therefore, hereby denied.

Sincerely,

Chuck Rosenberg,

Acting Administrator

Attachments:

Preliminary Note Regarding Treaty Considerations

Cover Letter from HHS to DEA Summarizing the Scientific and Medical Evaluation and Scheduling Recommendation for Marijuana.

U.S. Department of Health and Human Services (HHS)—Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

U.S. Department of Justice—Drug Enforcement Administration (DEA), Schedule of Controlled Substances: Maintaining Marijuana in Schedule I of the Controlled Substances Act, Background, Data, and Analysis: Eight Factors Determinative of Control and Findings Pursuant to 21 U.S.C. 812(b)

Dated: July 19, 2016.

Chuck Rosenberg,

Acting Administrator.

Preliminary Note Regarding Treaty Considerations

As the Controlled Substances Act (CSA) recognizes, the United States is a party to the Single Convention on Narcotic Drugs, 1961 (referred to here as the Single Convention or the treaty). 21 U.S.C. 801(7). Parties to the Single Convention are obligated to maintain various control provisions related to the drugs that are covered by the treaty. Many of the provisions of the CSA were enacted by Congress for the specific purpose of ensuring U.S. compliance with the treaty. Among these is a scheduling provision, 21 U.S.C. 811(d)(1). Section 811(d)(1) provides that, where a drug is subject to control under the Single Convention, the DEA Administrator (by delegation from the Attorney General) must ''issue an order controlling such drug under the schedule he deems most appropriate to carry out such [treaty] obligations, without regard to the findings required by [21 U.S.C. 811(a) or 812(b)] and without regard to the procedures prescribed by [21 U.S.C. 811(a) and (b)].''

Marijuana is a drug listed in the Single Convention. The Single Convention uses the term ''cannabis'' to refer to marijuana.[1] Thus, the DEA Administrator is obligated under section 811(d) to control marijuana in the

[1] Under the Single Convention, '''cannabis plant' means any plant of the genus Cannabis.'' Article 1(c). The Single Convention defines ''cannabis'' to include ''the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.'' Article 1(b). This definition of ''cannabis'' under the Single Convention is slightly less inclusive than the CSA definition of ''marihuana,'' which includes all parts of the cannabis plant except for the mature stalks, sterilized seeds, oil from the seeds, and certain derivatives thereof. *See* 21 U.S.C. 802(16). Cannabis and cannabis resin are included in the list of drugs in Schedule I and Schedule IV of the Single Convention. In contrast to the CSA, the drugs listed in Schedule IV of the Single Convention are also listed in Schedule I of the Single Convention and are subject to the same controls as Schedule I drugs as well as additional controls. Article 2, par. 5

schedule that he deems most appropriate to carry out the U.S. obligations under the Single Convention. It has been established in prior marijuana rescheduling proceedings that placement of marijuana in either schedule I or schedule II of the CSA is ''necessary as well as sufficient to satisfy our international obligations'' under the Single Convention. *NORML* v. *DEA,* 559 F.2d 735, 751 (D.C. Cir. 1977). As the United States Court of Appeals for the D.C. Circuit has stated, ''several requirements imposed by the Single Convention would not be met if cannabis and cannabis resin were placed in CSA schedule III, IV, or V.'' [2] *Id.* Therefore, in accordance with section 811(d)(1), DEA must place marijuana in either schedule I or schedule II.

Because schedules I and II are the only possible schedules in which marijuana may be placed, for purposes of evaluating this scheduling petition, it is essential to understand the differences between the criteria for placement of a substance in schedule I and those for placement in schedule II. These criteria are set forth in 21 U.S.C. 812(b)(1) and (b)(2), respectively. As indicated therein, substances in both schedule I and schedule II share the characteristic of ''a high potential for abuse.'' Where the distinction lies is that schedule I drugs have ''no currently accepted medical use in treatment in the United States'' and ''a lack of accepted safety for use of the drug . . . under medical supervision,'' while schedule II drugs do have ''a currently accepted medical use in treatment in the United States.'' [3]

Accordingly, in view of section 811(d)(1), this scheduling petition turns on whether marijuana has a currently accepted medical use in treatment in the United States. If it does not, DEA must, pursuant to section 811(d), deny the petition and keep marijuana in schedule I.

As indicated, where section 811(d)(1) applies to a drug that is the subject of a rescheduling petition, the DEA Administrator must issue an order controlling the drug under the schedule he deems most appropriate to carry out United States obligations under the Single Convention, without regard to the findings required by sections 811(a) or 812(b) and without regard to the procedures prescribed by sections 811(a) and (b). Thus, since the only determinative issue in evaluating the present scheduling petition is whether marijuana has a currently accepted medical use in treatment in the United States, DEA need not consider the findings of sections 811(a) or 812(b) that have no bearing on that determination, and DEA likewise need not follow the procedures prescribed by sections 811(a) and (b) with respect to such irrelevant findings. Specifically, DEA need not evaluate the relative abuse potential of marijuana or the relative extent to which abuse of marijuana may lead to physical or psychological dependence.

As explained below, the medical and scientific evaluation and scheduling recommendation issued by the Secretary of Health and Human Services concludes that marijuana has no currently accepted medical use in treatment in the United States, and the DEA Administrator likewise so concludes. For the reasons just indicated, no further analysis beyond this consideration is required. Nonetheless, because of the widespread public interest in understanding all the facts relating to the harms associated with marijuana, DEA is publishing here the entire medical and scientific analysis and scheduling evaluation issued by the Secretary, as well as DEA's additional analysis.

Department of Health and Human Services, Office of the Secretary Assistant Secretary for Health, Office of Public Health and Science Washington DC 20201.

June 25, 2015.

The Honorable Chuck Rosenberg
Acting Administrator, Drug Enforcement Administration, U.S. Department of Justice, 8701 Morrissette Drive, Springfield, VA 22152

Dear Mr. Rosenberg:

Pursuant to the Controlled Substances Act (CSA, 21 U.S.C. 811(b), (c), and (f)), the Department of Health and Human Services (HHS) is recommending that marijuana continue to be maintained in Schedule I of the CSA.

The Food and Drug Administration (FDA) has considered the abuse potential and dependence-producing characteristics of marijuana.

Marijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1). As discussed in the enclosed analyses, 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. Accordingly, HHS recommends that marijuana be maintained in Schedule I of the CSA. Enclosed are two documents prepared by FDA's Controlled Substance Staff (in response to petitions filed in 2009 by Mr. Bryan Krumm and in 2011 by Governors Lincoln D. Chafee and Christine O. Gregoire) that form the basis for the recommendation. Pursuant to the requests in the petitions, FDA broadly evaluated marijuana, and did not focus its evaluation on particular strains of marijuana or components or derivatives of marijuana.

FDA's Center for Drug Evaluation and Research's current review of the available evidence and the published clinical studies on marijuana demonstrated that since our 2006 scientific and medical evaluation and scheduling recommendation responding to a previous DEA petition, research with marijuana has progressed. However, the available evidence is not sufficient to determine that marijuana has an accepted medical use. Therefore, more research is needed into marijuana's effects, including potential medical uses for marijuana and its derivatives. Based on the current review, we identified several methodological challenges in the marijuana studies published in the literature. We recommend they be addressed in future clinical studies with marijuana to ensure that valid scientific data are generated in studies evaluating marijuana's safety and efficacy for therapeutic use. For example, we recommend that studies need to focus on consistent administration and reproducible dosing of marijuana, potentially through the use of administration methods other than smoking. A summary of our review of the published literature on the clinical uses of marijuana, including recommendations for future studies, is attached to this document.

FDA and the National Institutes of Health's National Institute on Drug Abuse (NIDA) also believe that work continues to be needed to ensure support by the federal government for the efficient conduct of clinical research using marijuana. Concerns have been raised about whether the existing federal regulatory system is flexible enough to respond to increased interest in research into the potential therapeutic uses of marijuana and marijuana-derived drugs. HHS welcomes an opportunity to continue to explore these concerns with DEA.

Should you have any questions regarding theses recommendations, please contact Corinne P. Moody, Science Policy Analyst, Controlled Substances Staff, Center for Drug Evaluation and Research, FDA, at (301) 796–3152.

Sincerely yours,

Karen B. DeSalvo, MD, MPH, MSc
Acting Assistant Secretary for Health

Enclosure:

Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

[2] The Court further stated: ''For example, [article 31 paragraph 4 of the Single Convention] requires import and export permits that would not be obtained if the substances were placed in CSA schedules III through V. In addition, the quota and [recordkeeping] requirements of Articles 19 through 21 of the Single Convention would be satisfied only by placing the substances in CSA schedule I or II.'' *Id.* n. 71 (internal citations omitted).

[3] As DEA has stated in evaluating prior marijuana rescheduling petitions, ''Congress established only one schedule, schedule I, for drugs of abuse with 'no currently accepted medical use in treatment in the United States' and 'lack of accepted safety for use . . . under medical supervision.' 21 U.S.C. 812(b).'' 76 FR 40552 (2011); 66 FR 20038 (2001).