

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Chapter II

[Docket No. DEA-352N]

Denial of Petition to Initiate Proceedings To Reschedule Marijuana

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

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

SUMMARY: By letter dated June 21, 2011, the Drug Enforcement Administration (DEA) denied a petition to initiate rulemaking proceedings to reschedule marijuana.¹ Because 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 (denying the petition), along with the supporting documentation that was attached to the letter.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone (202) 307-7165.

SUPPLEMENTARY INFORMATION:

June 21, 2011.

Dear Mr. Kennedy:

On October 9, 2002, 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 as cannabis in schedule III, IV or V.

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

(1) Cannabis has an accepted medical use in the United States;

(2) Cannabis is safe for use under medical supervision;

(3) Cannabis has an abuse potential lower than schedule I or II drugs; and

(4) Cannabis has a dependence liability that is lower than schedule I or II drugs.

In accordance with the CSA rescheduling provisions, after gathering the necessary data, DEA requested a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human

Services (DHHS). DHHS 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, DHHS recommended that marijuana remain in schedule I. The scientific and medical evaluation and scheduling recommendation that DHHS submitted to DEA is attached hereto.

Based on the DHHS 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 DHHS 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.* According to established case law, marijuana has no "currently accepted medical use" because: 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. 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.

You also argued that cannabis has a dependence liability that is lower than schedule I or II drugs. Findings as to the physical or psychological dependence of a drug are only one of eight factors to be considered. As discussed further in the attached documents, DHHS states that long-term, regular use of marijuana can lead to physical dependence and withdrawal following discontinuation, as well as psychic addiction or dependence.

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).

Accordingly, and as set forth in detail in the accompanying DHHS 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,

Michele M. Leonhart,
Administrator.

Attachments:

Marijuana. Scheduling Review Document: Eight Factor Analysis

Basis for the recommendation for maintaining marijuana in schedule I of the Controlled Substances Act

Date: June 30, 2011

Michele M. Leonhart
Administrator

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

December 6, 2006.

The Honorable Karen P. Tandy
Administrator, Drug Enforcement
Administration, U.S. Department of
Justice, Washington, D.C. 20537

Dear Ms. Tandy:

This is in response to your request of July 2004, and pursuant to the Controlled Substances Act (CSA), 21 U.S.C. 811(b), (c), and (f), the Department of Health and Human Services (DHHS) recommends that marijuana continue to be subject to control under Schedule I of the CSA.

Marijuana is currently controlled under Schedule I of the CSA. Marijuana continues to meet 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 attached analysis, marijuana has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and has a lack of an accepted level of safety for use under medical supervision. Accordingly, HHS recommends that marijuana continue to be subject to control under Schedule I of the CSA. Enclosed is a document prepared by FDA's Controlled Substance Staff that is the basis for this recommendation.

Should you have any questions regarding this recommendation, please contact Corinne P. Moody, of the Controlled Substance Staff, Center for Drug Evaluation and Research. Ms. Moody can be reached at 301-827-1999.

Sincerely yours,
John O. Agwunobi,
Assistant Secretary for Health.

Enclosure:

¹ Note that "marihuana" is the spelling originally used in the Controlled Substances Act (CSA). This document uses the spelling that is more common in current usage, "marijuana."