

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA-205F]

RIN 1117-AA55

Clarification of Listing of
“Tetrahydrocannabinols” in Schedule IAGENCY: Drug Enforcement
Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is revising the wording of the DEA regulations to clarify that the listing of “Tetrahydrocannabinols” (THC) in schedule I of the Controlled Substances Act (CSA) and DEA regulations refers to both natural and synthetic THC.

DATES: This final rule becomes effective on April 21, 2003.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:

What Does This Rule Accomplish and
by What Authority Is It Being Issued?

This final rule clarifies that, under the CSA and DEA regulations, the listing of “Tetrahydrocannabinols” in schedule I refers to both natural and synthetic THC.

This rule is being issued pursuant to 21 U.S.C. 811, 812, and 871(b). Sections 811 and 812 authorize the Attorney General to establish the schedules in accordance with the CSA and to publish amendments to the schedules in the Code of Federal Regulations, part 1308 of title 21. Section 871(b) authorizes the Attorney General to promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient enforcement of his functions under the CSA. These functions vested in the Attorney General by the CSA have been delegated to the Administrator and Deputy Administrator of DEA. 21 U.S.C. 871(a); 28 CFR 0.100(b) and 0.104, appendix to subpart R, sec. 12.

Why Is There A Need To Clarify The
Meaning of “Tetrahydrocannabinols”?

As DEA explained in its October 9, 2001 interpretive rule (66 FR 51530; hereafter “interpretive rule”), it is DEA’s interpretation of the plain language of the CSA and DEA regulations that the

listing of “Tetrahydrocannabinols” in schedule I refers to both natural and synthetic THC. Despite the wording of the statute, some members of the public were under the impression (prior to the publication of the interpretive rule) that the listing of “Tetrahydrocannabinols” in schedule I includes only synthetic THC—not natural THC. To eliminate any uncertainty, DEA is hereby revising the wording of its regulations to refer expressly to both natural and synthetic THC.

Why Should Natural THC Be
Considered a Controlled Substance?

There are several reasons why natural THC should be considered a controlled substance. First, as explained in the interpretive rule, it is evident from the plain language of the CSA that Congress intended all THC—natural or synthetic—to be a schedule I controlled substance. Congress did so by listing “Tetrahydrocannabinols” in schedule I of the CSA—without limiting “Tetrahydrocannabinols” to either natural or synthetic form. 21 U.S.C. 812(c), Schedule I(c)(17). The basic dictionary definition of the word “tetrahydrocannabinols” refers collectively to a category of chemicals—regardless of whether such chemicals occur in nature or are synthesized in the laboratory.¹

Second, every molecule of THC has identical physical and chemical properties and produces identical psychoactive effects, regardless of whether it was formed in nature or by laboratory synthesis.² Likewise, a product that contains THC in a given formulation will cause the same reaction to the human who ingests it regardless of whether the THC is natural or synthetic. Indeed, some researchers are currently investigating the possibility of using natural THC (extracted from cannabis plants) in drug products.³

¹ For example, Merriam-Webster’s Collegiate Dictionary (10th ed. 1999) defines “THC” as “a physiologically active chemical C₂₁H₃₀O₂ from hemp plant resin that is the chief intoxicant in marijuana—called also tetrahydrocannabinol;” this definition does not mention synthetic THC.

² In this context, “every molecule of THC” refers to every molecule of the same isomer of THC. For example, all molecules of 9-(trans)-THC are identical, regardless of whether they are natural or synthetic.

It should also be noted that “Tetrahydrocannabinols” refers to a class of substances which includes 9-(trans)-THC, its isomers, and other related substances. Collectively, this class will be referred to in this document as “THC,” unless otherwise indicated.

³ At present, Marinol® is the only THC-containing drug product that has been approved for marketing by FDA. Marinol® contains synthetic dronabinol (an isomer of THC) in sesame oil and encapsulated in soft gelatin capsules. This product

Third, regardless of its source, THC meets the criteria for classification in schedule I of the CSA. It is an hallucinogenic substance with a high potential for abuse and no currently accepted medical use.⁴ See 21 U.S.C. 812(b)(1). Thus, for purposes of CSA scheduling, there is no basis for distinguishing natural THC from synthetic THC.

Fourth, to ignore the foregoing considerations and to treat natural THC as a noncontrolled substance would provide a loophole in the law that might be exploited by drug traffickers. If natural THC were a noncontrolled substance, those portions of the cannabis plant that are excluded from the CSA definition of marijuana (the stalks and sterilized seeds of the plant) would be legal, noncontrolled substances—regardless of their THC content. As a result, it would be legal to import into the United States, and to possess, unlimited quantities of cannabis stalks and sterilized seeds—again, regardless of their THC content. Anyone could then obtain this raw cannabis plant material to produce an extract of THC—all without legal consequence. This would give drug traffickers an essentially limitless supply of raw plant material from which they could produce large quantities of a highly potent extract that would be considered a noncontrolled substance and, therefore, entirely beyond the reach of law enforcement. To provide such a safe harbor to drug traffickers would be plainly at odds with the purpose and structure of the CSA.⁵

Does This Rule Change the Legal Status
of “Hemp” Products?

This rule does not change the legal status of so-called “hemp” products (products made from portions of the cannabis plant that are excluded from the CSA definition of marijuana).

has been approved for the treatment of nausea and vomiting associated with cancer chemotherapy as well as the treatment of anorexia associated with weight loss in patients with AIDS. See 64 FR 35928 (1999) (DEA final order transferring Marinol® from schedule II to schedule III).

⁴ There are no FDA-approved drug products that consist solely of THC. However, as stated in the preceding footnote, the FDA has approved a drug product (Marinol®), which contains synthetic THC with other ingredients in a specified product formulation.

⁵ As one United States Court of Appeals has stated, “a reading of the [CSA] and its legislative history makes it apparent that Congress, in legislating against drug use, intended to encompass every act and activity which could lead to proliferation of drug traffic. Nothing in the statute indicates any congressional intent to limit the reach of this legislation, which is described in its title as ‘Comprehensive.’” *United States v. Everett*, 700 F.2d 900, 907 (3d Cir. 1983) (internal citations omitted).