

DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1308**

[DEA-205]

RIN 1117-AA55

**Clarification of Listing of
“Tetrahydrocannabinols” in Schedule I****AGENCY:** Drug Enforcement Administration, Justice.**ACTION:** Proposed rule and request for comments.

SUMMARY: In a separate document published today in the **Federal Register**, the Drug Enforcement Administration (DEA) issued an interpretive rule stating that under the Controlled Substances Act (CSA) and DEA regulations, any product that contains any amount of tetrahydrocannabinols (THC) is a schedule I controlled substance, even if such product is made from portions of the cannabis plant that are excluded from the CSA definition of “marihuana.” (Hereafter “the interpretive rule”.) Consistent with the interpretive rule, this document proposes to revise the wording of the DEA regulations to clarify that the listing of “Tetrahydrocannabinols” in schedule I of the CSA refers to both natural and synthetic THC. In a third **Federal Register** document issued today (immediately following this document), DEA is issuing an interim rule exempting from the application of the CSA certain industrial products, processed plant materials, and animal feed mixtures made from those portions of the cannabis plant that are excluded from the CSA definition of marijuana, to the extent such products and plant materials contain THC but are not used, or intended for use, for human consumption. The interim rule also provides a 120-day grace period for persons to dispose of existing inventories of THC-containing “hemp” products that are not exempted from control.

DATES: Comments must be received by DEA on or before December 10, 2001.

ADDRESSES: Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537; Attention: DEA Federal Register Representative/CCD.

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

This proposed 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. The functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 21 U.S.C. 871(a); 28 CFR 0.100.

Why Is There a Need To Clarify the Meaning of “Tetrahydrocannabinols”?

It has become evident from correspondence that DEA has received in recent months that some members of the public are under the impression that the listing of “Tetrahydrocannabinols” in schedule I of the CSA and DEA regulations refers only to synthetic—but not natural—THC. As explained in detail in the interpretive rule, it is DEA’s interpretation of the plain language of the CSA and DEA regulations, and the legislative history, that the listing of “Tetrahydrocannabinols” in schedule I refers to both natural and synthetic THC. To eliminate any uncertainty, DEA is proposing to revise the wording of its regulations to refer expressly to both natural and synthetic THC.

While This Proposed Rule Is Pending, What Is the Current Legal Status of “Hemp” Products?

As set forth in the interpretive rule, DEA interprets the current CSA and DEA regulations such that any product that contains any amount of tetrahydrocannabinols is a schedule I controlled substance, even if such product is a “hemp” product (i.e., a product made from portions of the cannabis plant that are excluded from the CSA definition of marijuana). However, as set forth in the interim rule, DEA is today exempting from control certain industrial “hemp” products, processed cannabis plant materials, and

animal feed mixtures containing sterilized cannabis seeds, provided such items are not used, or intended for use, for human consumption. With the exception of such exempted products and materials, all other “hemp” products and materials that contain any amount of THC remain schedule I controlled substances.

As specified in the interim rule, a 120-day grace period is being provided for persons to dispose of existing inventories of THC-containing “hemp” products that are not exempted from control.

Regulatory Certifications

Certain provisions of federal law and executive orders (specified below) require the agency to assess how a proposed rule might impact the economy, small businesses, and the states. (Hereafter in this document, these provisions will be referred to collectively as the “certification provisions.”) The certification provisions must be considered in light of the nature of this rule. This rule merely proposes to revise the wording of the DEA regulations to clarify for the public the agency’s understanding of existing law. In other words, through this proposed rule, DEA is implementing what it understands to be the mandate of Congress under the CSA. (This mandate is that every substance containing THC be listed in schedule I, unless the substance is specifically exempted from control or listed in another schedule.) Regardless of how this proposed rule might impact the economy, small businesses, or the states, DEA has no choice but to carry out such mandate.

Furthermore, when Congress enacted the CSA, it created a system of controls that was comprehensive in scope to protect the health and general welfare of the American people. Incidental restrictions on economic activity resulting from enforcement of the CSA have never been viewed as a proper basis to cease such enforcement. The certification provisions are no exception to this rule.

Moreover, one of the chief aims of the certification provisions is to ensure that agencies consider the potential economic ramifications of imposing new regulations. The proposed rule, however, would not create any new category of regulation governing the handling of controlled substances. Rather, the proposed rule merely helps to clarify what products are, or are not, subject to existing CSA regulations.

In a similar vein, it must be taken into account that this proposed rule does not alter existing legal obligations and rights

of members of the public. Since the proposed rule merely codifies DEA's interpretation of existing law, the legal status of THC-containing "hemp" products is unchanged by this proposed rule. Therefore, this proposed rule has no impact on any ongoing lawful economic activity in the United States. No THC-containing product that may be distributed under current United States law will become prohibited under the rules DEA is proposing and issuing today. Nor will the proposed rule impose any new regulation over such lawful products. Thus, this proposed rule has no economic impact for purposes of the certification provisions.

DEA recognizes, however, that some members of the public are either unaware of the current status of THC-containing products under federal law or disagree with DEA's interpretation of such law. As a result, there is ongoing economic activity in the United States related to the marketing of "hemp" products—despite the fact that such products are prohibited under current law to the extent they result in THC entering the human body. This proposed rule is intended to discourage such illegal trade in THC-containing products by clarifying the law. If this proposed rule succeeds in doing so, it will impact certain THC-related economic activity. However, since only unlawful economic activity will be affected, this impact should not preclude the promulgation of the rule.

If one were to assume, however, for the sake of argument, that this proposed rule would indeed change (not merely clarify) existing law, DEA would be required to conduct the economic assessments in accordance with the certification provisions. I.e., if one assumes that, prior to the issuance of this rule, it was lawful to manufacture and distribute all "hemp" products whose use resulted in THC entering the human body, then the certification provisions require DEA to assess the extent of such economic activity that would become prohibited under the proposed rule.

To conduct such an economic assessment, certain assumptions are made here. First, it is assumed that all products that are marketed as containing "hemp," "hempseed," or "hemp oil" are, in fact, made using portions of the cannabis plant.¹ Next, it

is assumed that legitimate industrial "hemp" products—such as paper, rope, clothing, and animal feed mixtures—need not be considered in this economic assessment because they are exempted from control under the interim rule that DEA is issuing today. Finally, to err on the side of inclusiveness, economic activity related to all personal care "hemp" products will be considered here, even though (as explained in the interim rule) DEA believes that most such products meet the criteria for exemption under the interim rule.

Given the foregoing assumptions, the "hemp" products that will be affected economically by the proposed rule can be placed into three categories: Edible "hemp" products, personal care "hemp" products, and "hemp" raw materials. The economic activity related to each of these three categories is addressed separately below.

As a general matter, neither edible "hemp" products nor personal care "hemp" products have a long-standing and established history in the United States that provides a reliable source of market data. DEA found no official economic data on such products upon inquiring with the United States Department of Commerce, the United States Customs Service, and the Small Business Administration. A recent report of the United States Department of Agriculture (USDA) does contain some general information about the "hemp" products industry. In addition, one company that distributes "hemp" personal care products has provided some information to DEA about its sales. DEA was also able to obtain some information from the Internet, as specified below. Relying on an Internet search for economic statistics on the "hemp" products industry, however, has obvious limitations. Accordingly, DEA urges any manufacturer or distributor of "hemp" products to submit within the comment period any relevant data and supporting documents that it wishes DEA to consider in assessing the economic impact of the proposed rule.

Edible "Hemp" Products

As stated in the interim rule, all edible "hemp" products containing THC are not exempted from control, since use of these products results in THC entering the human body. Such products would remain prohibited schedule I controlled substances under the proposed rule.

that the product truly contains such ingredient. If a product says "hemp" on the label but actually contains no portion of the cannabis plant, it is not affected by this proposed rule.

A recent USDA report states the following about edible "hemp" products: Companies are using hemp seed in their products. Natural-product magazines, such as the Natural Food Merchandiser and Organic & Natural News, have advertised products containing hemp ingredients such as roasted hull seed, nutrition bars, tortilla chips, pretzels, and beer. At least two breweries in the United States, as well as breweries in Canada, Germany, and Switzerland, make hemp beer. One article touts hulled hemp seeds as more shelf-stable than flax and more digestible than soybeans and finds the seeds in snacks, spreads, salad dressings, cheese, and ice cream. The market potential for hemp seed as a food ingredient is unknown. However, it probably will remain a small market, like those for sesame and poppy seeds. Some consumers may be willing to pay a higher price for hemp-seed-containing products because of the novelty, but otherwise hemp seed will have to compete on taste and functionality with more common food ingredients. Industrial Hemp in the United States: Status and Market Potential (January 2000) (citations omitted) (hereafter, "USDA report").

DEA's search of the Internet indicates that at least 50 different companies located in the United States manufacture or distribute edible "hemp" products. One such company located in California claims on its website that its "hempseed bars" are "the top selling hemp food in the U.S." According to the website, the company has sold over 125,000 "hempseed bars." The advertised price is approximately \$40 for a box of 24 bars (\$1.67 per bar). Using these figures for purposes of estimation, the company's total revenues from the sales of these bars is approximately \$200,000. DEA is unable to determine from the company's website the time period during which these sales arose. Nor could DEA ascertain from the website the extent of revenue that the company might be generating from sales of other edible "hemp" products. If, however, the company's "hempseed bars" are indeed "the top selling hemp food in the U.S.," one might preliminarily assume that the sales of this product represent at least one percent of all sales of edible "hemp" products in the United States.² If so, then the approximately \$200,000 per year that the company takes in on

¹ The word "hemp" is sometimes used to refer not only to the cannabis plant, but also to other plants grown for fiber, such as *Musa textilis* ("manila hemp"), *Agave sisalana* ("sisal hemp"), and *Crotalaria juncea* ("sunn hemp"), none of which contains any controlled substances. Furthermore, that the manufacturer placed the word "hemp" on the product label does not guarantee

² The top-selling edible "hemp" product might represent significantly more than one percent of the total market. However, the one-percent assumption is made so as not to underestimate the entire market.

the sale of its "hempseed bars" is at least one percent of the total sales of edible "hemp" products in the United States. If so, then the total sales of edible "hemp" products in the United States is no more than \$20 million. DEA recognizes that this estimate is based on rough assumptions and might therefore be far from the actual sales figures. Accordingly, DEA again urges any members of the public with reliable data and documentation to submit such information to DEA during the comment period.

Based on the information that DEA has thus far obtained, the number of employees in the edible "hemp" products industry cannot be accurately determined. To make a very rough estimate, if there were 100 such companies in the United States, each of which had five employees whose jobs were dependent on the sale of edible "hemp" products, then 500 jobs would be terminated if the companies followed the proposed rule and ceased their production and distribution of such products. Again, DEA will consider any relevant data and supporting documentation received during the comment period and adjust these economic assessments accordingly.

Personal Care "Hemp" Products

As noted above, to err on the side of inclusion, all personal care "hemp" products are being considered for purposes of this economic assessment, even though (as explained in the interim rule) it seems likely that most "hemp" personal care products meet the criteria for exemption under the interim rule.

DEA's search of the Internet indicates that at least 34 firms manufacture or distribute "hemp" personal care products in the United States. Of these 34 firms, the one that appears to be the largest is a company based outside of the United States that sells a variety of personal care products worldwide. This company has advised DEA that four percent of its sales are attributable to "hemp" personal care products. Based on additional statistics provided by the company, it appears that the total of its retail sales of "hemp" products in the United States is approximately \$10 million per year.

According to the 1997 Economic Census of Manufacturing ("Manufacturing Census") published by the United States Census Bureau, in the category of toilet preparations, the total value of shipments in the United States of creams, lotions, and oils in 1997 was approximately \$3.5 billion, while the total value of shipments of shampoos was approximately \$2.4 billion. (The Manufacturing Census contains no

specific data on "hemp" products.) It seems reasonable to assume that no more than 0.5 percent of all such creams, lotions, oils and shampoos are "hemp" products.³ Thus, it seems reasonable to conclude that the total shipments of "hemp" personal care products in 1997 was no more than \$30 million. The Manufacturing Census also indicates that there are 134 establishments employing approximately 22,000 persons in the cream, lotion, oil, and hair preparations industries. If 0.5 percent of these companies and jobs were dependent on the sale of "hemp" products, this would represent a total of approximately seven firms and 110 total jobs.

"Hemp" Raw Materials

For purposes of this part of the economic assessment, three categories of "hemp" raw materials used for industrial purposes are considered: unprocessed stalks, pure sterilized⁴ seeds (not mixed with other ingredients), and unprocessed seed oil.

Unprocessed Stalks

It appears that no significant quantities of unprocessed cannabis stalks are imported into the United States for industrial purposes. The USDA report (and documents cited therein) suggests that such stalks are generally processed into fiber or fabrics before they are imported into the United States. Such processed materials are exempted from control under the interim rule and, therefore, need not be considered for purposes of this economic assessment.

Pure Sterilized Seeds

According to a recent study by the University of Kentucky,⁵ the total

³ As noted above, the company that appears to be the largest retailer of "hemp" personal care products in the United States has advised DEA that such products account for four percent of its sales of personal care products. It seems certain that most retail stores in the United States that sell personal care items do not carry any "hemp" personal care products. Thus, it seems likely that "hemp" personal care products actually account for far less than 0.5 percent of all personal care products sold in the United States.

⁴ Unsterilized cannabis seeds (which are capable of germination) fit within the CSA definition of marijuana regardless of their THC content. Therefore, unsterilized seeds are considered a schedule I controlled substance. Accordingly, the control status of unsterilized seeds is unaffected by this proposed rule and need not be considered in this economic analysis. Also, sterilized seeds that mixed with seeds from other plants in an animal feed product are exempted from control under the interim rule and are, therefore, not being considered in this economic analysis. Economic activity related to sterilized seeds used in edible hemp products and personal care products is addressed in the preceding section of this document.

⁵ Thompson, Eric C., Mark C. Berger, & Steven Allen, *Economic Impact of Industrial Hemp in*

demand for "hemp" seed in North America is approximately 1,300 tons per year. The University of Kentucky study indicates that the price of such seed is no more than \$0.39 per pound. Using these figures, the total value of the demand for "hemp" seed in North America is approximately \$1 million. The United States share of this demand is only a portion of this figure. Moreover, where sterilized cannabis seeds are sold in an animal feed product that contains other ingredients (not derived from the cannabis plant), the product is exempted from control under the interim rule and, therefore, need not be considered for purposes of this economic assessment. Accordingly, it can be inferred for purposes of this economic assessment that far less than \$1 million worth of seeds will be impacted by the proposed rule.

One significant portion of the "hemp" seeds imported into the United States is that used in bird seed. The University of Kentucky study states that 60 tons of "hemp" seed were imported into the United States for use in bird seed in 1990, and that such demand has decreased in recent years. Even if the current demand for "hemp" bird seed remained at 60 tons per year, this would constitute less than one percent of all bird seed imported into the United States in 1999, according to data compiled by the United States International Trade Commission (USITC).⁶ The USITC data indicates that the total value of all bird seed imported in the United States in 1999 was approximately \$7.7 million. If one percent of this were "hemp" seed, this would mean that approximately \$77,000 worth of "hemp" bird seed is imported into the United States per year. It is worth repeating here that any bird seed that consists of a mixture of sterilized cannabis seed and other noncannabis ingredients is exempted from control under this interim rule and can, therefore, be excluded from this economic assessment.

Unprocessed Seed Oil

Based on the USDA report and the University of Kentucky study, it appears that no significant amount of

Kentucky, University of Kentucky, Center for Business and Economic Research, July 1998. [6]: See <http://dataweb.usitc.gov>. [7]: The economic activity related to "hemp" oil used in edible products and personal care products is addressed in preceding sections of this document. Moreover, as noted above, processed "hemp" oil that is not used or intended for use for human consumption, and is not readily converted for human consumption, is exempted from control under the interim rule and is, therefore, not considered in this economic assessment.

⁶ See <http://dataweb.usitc.gov>.

unprocessed "hemp" seed oil is imported into the United States for use in manufacturing industrial products (such as paints, sealants, inks, and lubricating oils).⁷ However, as with all products potentially impacted by this proposed rule, DEA invites members of the public with relevant economic data to submit such information during the comment period.

Regulatory Flexibility Act

For the reasons provided above, the Administrator hereby certifies that this proposed rule will not have a significant impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. "605(b)). The economic activity that would be disallowed under this proposed rule is already illegal under DEA's interpretation of existing law. Even if one were to assume that such economic activity were legal under current law, the prohibition on such activity resulting from this proposed rule (summarized above) would not constitute significant impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act. Therefore, an initial regulatory flexibility analysis is not required for this proposed rule.

Executive Order 12866

This proposed rule has been drafted and reviewed in accordance with Executive Order 12866, Regulatory Planning and Review, § 1(b), Principles of Regulation. This rule has been determined to be a "significant regulatory action" under Executive Order 12866, § 3(f). Accordingly, this interim rule has been reviewed by the Office of Management and Budget for purposes of Executive Order 12866.

Executive Order 13132

This proposed rule does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this proposed rule does not have federalism implications warranting the application of Executive Order 13132.

⁷ The economic activity related to "hemp" oil used in edible products and personal care products is addressed in preceding sections of this document. Moreover, as noted above, processed "hemp" oil that is not used or intended for use for human consumption, and is not readily converted for human consumption, is exempted from control under the interim rule and is, therefore, not considered in this economic assessment.

Executive Order 12988—Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year. Therefore, no actions are necessary under the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

For the reasons provided above, this proposed rule is not likely to result in any of the following: an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. The economic activity disallowed under this proposed rule is already illegal under DEA's interpretation of existing law. Even if one were to assume that such economic activity were legal under current law, the prohibition on such activity resulting from this proposed rule would not render the rule a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. "804. Therefore, the provisions of SBREFA relating to major rules are inapplicable to this proposed rule. However, a copy of this proposed rule is being submitted to each House of the Congress and to the Comptroller General in accordance with SBREFA (5 U.S.C. 801).

Paperwork Reduction Act of 1995

This proposed rule does not involve collection of information within the meaning of the Paperwork Reduction Act of 1995.

Plain Language

In writing this proposed rule, DEA has attempted to use plain language in an easy-to-read manner, consistent with the June 1, 1998 directive of the President. See 63 FR 31885. If you have any suggestions to make this document easier to understand, call or write Patricia Good, Chief, Liaison and Policy Section, Office of Diversion Control,

Washington, DC 20537; telephone: (202) 307-7297.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs, Reporting and recordkeeping requirements.

Proposed Rule

Pursuant to the authority vested in the Attorney General under sections 201, 202, and 501(b) of the CSA (21 U.S.C. 811, 812, and 871(b)), delegated to the Administrator pursuant to section 501(a) (21 U.S.C. 871(a)) and as specified in 28 C.F.R. 0.100, the Administrator hereby orders that Title 21 of the Code of Federal Regulations, Part 1308, is proposed to be amended as follows:

PART 1308—[AMENDED]

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Section 1308.11(d)(27) is revised to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(27) Tetrahydrocannabinols 7370

Meaning tetrahydrocannabinols naturally contained in a plant of the genus *Cannabis* (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:

Δ¹ cis or trans tetrahydrocannabinol,
and their optical isomers
Δ⁶ cis or trans tetrahydrocannabinol,
and their optical isomers
Δ^{3,4} cis or trans tetrahydrocannabinol,
and its optical isomers

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

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Dated: October 2, 2001.

Asa Hutchinson,
Administrator.

[FR Doc. 01-25023 Filed 10-5-01; 8:45 am]

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