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21 CFR 1308

**Clarification of Listing of
“Tetrahydrocannabinols” in Schedule I
and Exemption From Control of Certain
Industrial Products and Materials Derived
From the Cannabis Plant; Final Rules**

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:

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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).

Rather, this rule clarifies provisions of the law and regulations that have been in effect since 1971. For the reasons provided in the interpretive rule, it is DEA's view that the CSA and DEA regulations have always (since their enactment more than 30 years ago) declared any product that contains any amount of tetrahydrocannabinols to be a schedule I controlled substance. This interpretation holds regardless of whether the product in question is made from "hemp" or any other material.

Nor does this rule add to, or subtract from, the exemptions issued by DEA in the October 9, 2001 interim rule. Every type of "hemp" product that was exempted from control under that interim rule will remain exempted following the finalization of this rule. Thus, given DEA's interpretation of current law (expressed in the interpretive rule), this rule does not change the legal status of any "hemp" product.

What Is the Difference Between This Final Rule and the Previously-Issued Interpretive Rule?

This final rule is a legislative rule. It is important to understand the difference between a legislative rule and an interpretive rule, such as the interpretive rule on THC that DEA issued on October 9, 2001. The following is a brief explanation of the difference between legislative rules and interpretive rules.

Under the Administrative Procedure Act (APA), agencies may issue interpretive rules to advise the public of how the agency interprets a particular provision of a statute or regulation which the agency administers.⁶ By definition, interpretive rules are simply the agency's announcement of how it interprets existing law. Interpretive rules are not new laws and are not binding on the courts. Even though courts often defer to an agency's interpretive rule, they are always free to choose otherwise.

Legislative rules, on the other hand, have the full force of law and are binding on all persons, and on the courts, to the same extent as a congressional statute.⁷ Because of this crucial difference, the APA requires agencies to engage in notice-and-comment proceedings before a legislative rule takes effect.⁸ By the

same reasoning, since interpretive rules do not have the full force of law and are not binding on the courts, the APA expressly allows agencies to issue interpretive rules without engaging in notice-and-comment. 5 U.S.C. 553(b)(A), (d)(2).

Consistent with these APA principles, DEA published the interpretive rule in October 2001 without notice and comment, whereas the legislative rule that is being finalized in this document has gone through notice and comment. As a result, this final rule will have the full force of law and be binding on the courts—just as with all the other DEA regulations that have gone through notice and comment.⁹ In contrast, the interpretive rule was not binding on the courts. The practical effect of this distinction can be seen by considering the following hypothetical scenarios. If, prior to the publication of this final rule, a federal prosecution was commenced based solely on DEA's interpretive rule, the presiding court would have been free to choose between applying DEA's interpretation or its own interpretation of the law. But once this rule becomes final, if a person were to refuse to abide by the regulation and a federal prosecution were commenced, the court would be required to apply the new regulation.¹⁰

Comments That DEA Received in Response to the Proposed Rule

Following publication of the proposed rule, DEA received comments from thousands of individuals and groups. The comments were in the form of original letters, form letters, petitions, and a cookbook. Those who submitted comments included companies that manufacture and distribute various "hemp" products, associations that represent such manufacturers and distributors, domestic and Canadian government officials, and individuals. These commenters expressed criticisms on a variety of issues. In accordance with the APA, DEA carefully considered all of the comments it received.

Most of the comments that DEA received relate to both the proposed rule (DEA 205; 66 FR 51535) and the interim rule (DEA 206; 66 FR 51539), which were published together (along with the interpretive rule) in the October 9, 2001 **Federal Register**. Those comments that

rule] that the APA requires it to comply with notice and comment").

⁹The DEA regulations are published in Title 21 of the Code of Federal Regulations, Part 1300.

¹⁰Legislative regulations are controlling on the courts unless they are "arbitrary, capricious, or manifestly contrary to the statute." *Chevron, U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984).

pertain primarily to DEA 205 are addressed in this final rule. Those comments that pertain primarily to DEA 206 are addressed in the final DEA 206 rule, which appears in a separate **Federal Register** document that immediately follows this document. Both DEA 205 and DEA 206 contain a summary of the pertinent comments, along with an explanation of how DEA considered them in deciding to finalize the rules.

The number of individuals and groups that participated in the comment process far exceeded the number of different issues raised. Many of the comments were similar to one another, partly because many persons submitted form letters or signed petitions written by groups which themselves submitted lengthy comments. In this document, together with the final rule finalizing the DEA 206 interim rule, DEA has addressed the major issues raised by the commenters. Some of these issues have already been addressed in the text that precedes this section. The remaining issues are addressed below and in the DEA 206 final rule.

Comments Expressing Legal Disagreement With the Proposed Rule

Many commenters disagreed with DEA's legal interpretation of those provisions of the CSA and DEA regulations that are relevant to the proposed rule. Specifically, these commenters disagreed with DEA's view that, under the plain language of the CSA, "any material, compound, mixture, or preparation, which contains any quantity of * * * Tetrahydrocannabinols (THC)" is a schedule I controlled substance. 21 U.S.C. 812(c), schedule I(c)(17); 21 CFR 1308.11(d)(27). These commenters asserted that THC content is irrelevant when it comes to products made from portions of the cannabis plant that are excluded from the definition of marijuana. According to these commenters, DEA should allow the CSA definition of marijuana to dictate which portions of the cannabis plant are controlled substances. DEA addressed this issue in detail in the legal analysis contained in the interpretive rule. Nonetheless, many commenters asserted that their point of view is the correct reading of the law and should be substituted for that of DEA. DEA reexamined this issue in view of the comments. While recognizing that many proponents of "hemp" products are steadfast in their view that natural THC content is irrelevant in deciding what is a controlled substance, DEA continues to believe that its interpretation follows directly from the plain language of the

⁶ See *Shalala v. Guernsey Memorial Hosp.*, 514 U.S. 87, 99 (1995).

⁷ *National Latino Media Coalition v. F.C.C.*, 816 F.2d 785, 788 (D.C. Cir. 1987).

⁸ *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997) ("it is because the agency is engaged in lawmaking [when it issues a legislative

CSA and the DEA regulations and is consistent with the legislative history of the statute and regulations. Moreover, DEA believes that the analysis contained in the interpretive rule refutes all of the contrary legal arguments expressed in the comments. As the agency responsible for administering the CSA, it is DEA's obligation to ensure that the regulations clearly reflect what the agency believes are the purpose and intent of the Act.

Comments as to Whether This Rule Constitutes a Rescheduling Action

Some commenters expressed the view that this rule is a rescheduling action within the meaning of 21 U.S.C. 811 and that DEA should have gone through the procedures set forth in that section prior to issuing this rule.¹¹ These comments appear to be based on a misunderstanding of the nature of the procedures under section 811. By its express terms, section 811 applies only where DEA seeks to add a substance to a schedule or remove one from a schedule. For example, if DEA were seeking to move a controlled substance from schedule II to schedule III, the agency would be required to follow the procedures set forth in section 811. The final rule being published today, however, does not change the schedule of THC or any other controlled substance. To the contrary, when this final rule becomes effective, on April 21, 2003, THC will remain in the same schedule in which it has been since the enactment of the CSA in 1970: Schedule I.

Nor would engaging in the rescheduling procedures set forth in section 811 be consistent with the purpose of this rule. Section 811 sets forth the procedures to determine whether a particular substance meets the criteria for placement in a particular schedule. The purpose of this rule is not to determine whether THC meets the criteria for classification in schedule I; rather, this rule serves to clarify that the longstanding placement of THC in schedule I includes both natural and synthetic THC. There is no question about whether THC meets the criteria for placement in schedule I.¹² Even

¹¹ Under 21 U.S.C. 811, to change the schedule of a controlled substance, DEA must first request from the Secretary of Health and Human Services a scientific and medical evaluation and scheduling recommendation and follow additional procedures set forth in section 811. However, as discussed above, section 811 is inapplicable where, as in this final rule, DEA is not changing the schedule of a controlled substance.

¹² The criteria for placement in schedule I are: "no currently accepted medical use in treatment in the United States," "a lack of accepted safety for

those commenters who suggested that this rule should be issued under section 811 do not dispute that all THC (natural or synthetic) meets the criteria for placement in schedule I. As discussed above, the chemical THC has the identical physical and chemical properties, and produces the same psychoactive effects, regardless of whether it is natural or synthetic. For these reasons, section 811 is inapplicable to this rule.

Comments Regarding Poppy Seeds

Some of the commenters asserted that DEA should not take literally the plain language of the CSA: that "any material, compound, mixture, or preparation, which contains any quantity of * * * Tetrahydrocannabinols [THC]" is a schedule I controlled substance. To read this provision literally, some commenters said, would mean that poppy seeds must be considered controlled substances if they contain trace amounts of opiates (such as morphine, codeine, or thebaine). This concern is unfounded because, under the CSA and DEA regulations, substances that contain opiates are controlled differently than substances that contain schedule I hallucinogens (such as THC). It is true that poppy seeds are excluded from the definition of opium poppy (21 U.S.C. 802(19)) just as sterilized cannabis seeds are excluded from the definition of marijuana. However, while it is the case that "any material, compound, mixture, or preparation, which contains any quantity of" an hallucinogenic controlled substance is a controlled substance (21 U.S.C. 812(c), schedule I (c); 21 CFR 1308.11(d)), it is not the case that any material, compound, mixture, or preparation which contains any quantity of an opiate is a controlled substance. Rather, naturally-occurring opiates found in substances of vegetable origin are subject to control under the CSA only if they are extracted from the substances of vegetable origin. 21 U.S.C. 812(c), schedule II(a); 21 CFR 1308.12(b).¹³

Comments Regarding the Single Convention on Narcotic Drugs

Several commenters asserted that the proposed rule is impermissible in view of a certain provision of the Single Convention on Narcotic Drugs, 1961

use * * * under medical supervision," and "a high potential for abuse." 21 U.S.C. 812(b)(1).

¹³ Plant materials that are the source of narcotics, such as opium poppy, poppy straw, and opium, are specifically listed in schedule II. However, as stated above, the listing of opium poppy does not include poppy seeds, since the seeds are excluded from the definition of opium poppy.

("Single Convention"). The Single Convention, which the United States ratified in 1967, was designed to establish effective control over international and domestic traffic in controlled substances, and parties to the Convention are required to implement certain minimum measures. Article 28 of the Single Convention imposes on parties certain restrictions on the cultivation of the cannabis plant. However, paragraph 2 of Article 28 states that the Single Convention does not apply "to the cultivation of the cannabis plant exclusively for industrial purposes (fibre [sic] and seed) or horticultural purposes." Several commenters asserted that this provision means that the United States is prohibited from imposing any restrictions on "hemp." This assertion is incorrect.

The Single Convention sets minimum standards of drug control measures that the parties must apply—not maximum measures. Parties are free to impose whatever additional measures they believe are necessary to prevent the misuse, and illicit traffic in, controlled substances. Indeed, various provisions of the CSA go beyond the minimum measures required by the Single Convention. Congress's decision under the CSA to control anything that contains "any quantity" of THC is the decisive factor for purposes of this rule, regardless of whether a less restrictive rule would be permissible under the Single Convention.¹⁴

¹⁴ To fully address the distinctions between the control of cannabis under the Single Convention and the control of marijuana and THC under CSA would require a lengthy discussion. Such a discussion is unnecessary here because this rule is based on how THC is controlled under the CSA. Thus, there is no need to address here whether the reference in the Single Convention (Article 28, paragraph 2) to cannabis grown for "industrial" or "horticultural" purposes includes cannabis grown to make foods or beverages, or whether such reference is limited to non-human-consumption items such as rope, paper, textiles, industrial solvents, and birdseed.

A full analysis of the international drug control treaties would also require discussion of the Convention on Psychotropic Substances, 1971 (Psychotropic Convention). THC is a substance listed in the schedules of the Psychotropic Convention. Accordingly, the United States, as a party to the Psychotropic Convention, has certain obligations thereunder with respect to the control of THC. However, it is unnecessary to examine the scope of those obligations in this document because Congress stated expressly in United States domestic law that anything that contains "any quantity" of THC is a schedule I controlled substance, unless listed in another schedule or expressly exempted. Adherence to this rule and the corresponding provisions of the CSA ensures that the United States meets its obligations under the Psychotropic Convention with respect to THC.

Comments Regarding Trade Agreements

Some commenters expressed the view that the proposed rule violates certain obligations of the North American Free Trade Agreement (NAFTA) and the World Trade Organization (WTO) agreements. Many of these same commenters expressed these assertions to DEA before the proposed rule was published in October 2001. As a result, both before and after publication of the proposed rule, DEA sought the input of the Department of State and other components of the Executive Branch with the relevant expertise and responsibility for such matters and concluded that the proposed rule—which simply clarifies longstanding federal law with respect to schedule I hallucinogenic controlled substances—does not violate NAFTA or the WTO agreements.

One of the bases for these treaty claims asserted by commenters is the contention that the proposed rule provides more favorable treatment to United States and foreign, non-Canadian investors and their investments than to Canadian “hemp” investors and their investments in the United States. In reality, the rule applies to and treats all “hemp” industry investors and their investments the same—*i.e.*, regardless of nationality of ownership. No company (whether Canadian-owned, foreign but non-Canadian-owned, or United States-owned) can manufacture, distribute or market products used, or intended for use, for human consumption that contain any amount of THC. DEA has made no exception to this rule for any United States company or any foreign company.

Comments Requesting an Extension of the Comment Period

Some commenters asked DEA to extend the comment period. DEA did not do so for the following reasons. In the notice of the proposed rule, DEA provided a 60-day comment period from the date of the publication in the **Federal Register**, which allowed ample time for any interested persons to express their opinions.

DEA considered all comments that were postmarked within the comment period, even where the agency did not receive the comments until several months after the comment period closed.¹⁵ It is evident from the number

¹⁵ At the time the comment period closed, postal deliveries to DEA and other agencies were delayed after the widely-reported incidents of anthrax being sent through the mail. Because of this, although the proposed rule indicated that DEA would only consider comments received on or before December 10, 2001, the agency considered all comments postmarked by that date, even if they arrived late.

and variety of comments that were submitted, and the detailed nature of such comments, that a wide range of viewpoints was expressed to the agency during the comment period. Nearly all of the types of comments that were submitted during the comment period were repeated many times over by a number of commenters, which further indicates that interested parties have had sufficient opportunity to express their comments.

DEA provided the public with advance notice of the rules. In the year preceding the October 9, 2001 publication of the rules, DEA announced twice in the **Federal Register** that the agency would be issuing the proposed rule, along with the interpretive rule and the interim rule, and described the nature of the rules. See Department of Justice Unified Agenda, 66 FR 25624 (May 14, 2001), 65 FR 74024 (November 30, 2000). It is evident from the comments submitted on the proposed rule that the advance notice gave interested persons ample time to assemble and articulate their thoughts and opinions. Some of those persons who requested an extension of the comment period themselves submitted lengthy comments, indicating that they have already fully expressed their views. In light of these considerations, extending the comment period was unnecessary.

Comments Regarding Economic Impact of the Proposed Rule

Many commenters expressed concern about how the proposed rule might impact economically various businesses that deal in “hemp” products. These economic considerations are addressed in the next section of this document (regulatory certifications).

Regulatory Certifications

Certain provisions of Federal law and executive orders (specified below) require agencies to assess how their rules might impact the economy, small businesses, and the states. (Hereafter in this document, these provisions will be referred to collectively as the “certification provisions.”) DEA has conducted these certifications. However, before discussing the economics, the nature of this rule should be reiterated. This rule revises the wording of the DEA regulations to clarify for the public the agency’s understanding of longstanding federal law. In other words, through this rule, DEA is implementing what it believes 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 rule might impact the economy, small businesses, or the states, DEA must carry out the mandate.

It is also critical to bear in mind that only a very narrow category of “hemp” products will be prohibited under the rules that DEA is publishing today. As a result of the exemptions issued by DEA under the interim rule, all “hemp” products that do not cause THC to enter the human body are entirely exempted from control, regardless of their THC content. Thus, items such as “hemp” clothing, industrial solvents, personal care products, and animal feed mixtures are considered noncontrolled substances (not subject to any of the CSA requirements) regardless of their THC content. This rule therefore causes no economic impact whatsoever on such exempted products.

It also must be considered that when Congress enacted the CSA, it created a system of controls that was comprehensive in scope to protect the general welfare of the American people within the context of the Act.¹⁶ 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 principle.

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

DEA recognizes, however, that some members of the public disagree with DEA’s interpretation of the law with respect to THC. As a result, some companies may be continuing to market in the United States “hemp” food and beverage products that contain THC. Accordingly, for purposes of calculating the economic impact of these rules, DEA has assumed THC-containing “hemp” foods and beverages are lawful products until this rule becomes final.

In the regulatory certifications that accompanied the proposed rule, DEA explained in detail its analysis of the economic activity relating to “hemp” food and beverage products (referred to therein and hereafter in this document as “edible ‘hemp’ products”). 66 FR at 51536–51537. In that analysis, using

¹⁶ See 21 U.S.C. 801(2).

conservative assumptions (erring on the side of inclusiveness), DEA estimated that the total sales of edible “hemp” products in the United States is no more than \$20 million per year with no more than 500 persons employed in connection with these products. In the publication of the proposed rule, DEA urged any manufacturer or distributor of “hemp” products to submit during the comment period any data on this economic activity that might warrant adjustments to these estimates. The comments that DEA received suggest that the agency might have overestimated the amount of economic activity tied to edible “hemp” products. The highest estimate submitted by representatives of businesses that produce and distribute edible “hemp” products was that the total sales of such products in the United States is approximately \$6 million.

It also must be noted that not every such edible product marketed as a “hemp” product is necessarily prohibited under the rule being finalized today. As DEA stated repeatedly in the text accompanying the proposed rule and the interim rule, if a product says “hemp” on the label but contains no THC (or any other controlled substance), it is not a controlled substance and, therefore, not affected by this rule. At least one “hemp” food company claims that its products are THC-free.¹⁷ If this is correct, such products are not controlled substances and not prohibited by the CSA. Thus, even if the edible “hemp” products business is a \$6 million industry in the United States, some of that business might be able to continue under this final rule.

The one other category of products that might be impacted economically by this rule is that in which pure cannabis seeds are sold as birdseed. (As set forth in the interim rule, which is being finalized today, DEA is exempting animal feed mixtures containing sterilized cannabis seeds with other ingredients, but not pure sterilized cannabis seeds.) In the regulatory certifications attached to the proposed rule, DEA estimated that no more than

\$77,000 worth of birdseed that contains cannabis seeds is imported into the United States for sale in this country. It appears likely that most of this birdseed is sold in a mixture that is exempted under the interim rule. Accordingly, the total amount of pure “hempseeds” sold as birdseed in this country is probably much less than \$77,000.

Regulatory Flexibility Act

For the reasons provided above, the Acting Administrator hereby certifies that this 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 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 rule (summarized above) would not constitute significant impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act. Therefore, a final regulatory flexibility analysis is not required for this rule.

Executive Order 12866

This 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 rule has been reviewed by the Office of Management and Budget for purposes of Executive Order 12866.

Executive Order 13132

This 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 rule does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 12988—Civil Justice Reform

This 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 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 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 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 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 rule. However, a copy of this rule has been sent to the Office of Advocacy, Small Business Administration. Further, a copy of this final rule will be 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 rule does not involve collection of information within the meaning of the Paperwork Reduction Act of 1995.

List of Subjects in 21 CFR Part 1308

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

Final 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 and Deputy Administrator pursuant to section 501(a) (21 U.S.C. 871(a)) and as specified in 28 CFR 0.100 and 0.104, appendix to subpart R, sec. 12, the Acting Administrator hereby orders that Title 21 of the Code of Federal Regulations, part 1308, be amended as follows:

PART 1308—[AMENDED]

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

¹⁷ On January 28, 2002, a company that sells “hemp” food products issued the following statement on its website (<http://www.thehempnut.com>): It is the position of HempNut, Inc. and the Hemp Food Association (HFA) that this Rule [published by DEA on October 9, 2001] is merely a clarification and confirmation of the basis under which DEA, US Customs, and all responsible hempseed importers have already been operating under for quite some time, namely, that hempseed products may not contain tetrahydrocannabinol (THC). A survey of hempseed importers revealed that all were in full compliance with the Rule, and have no THC in their products.

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:

- 1 cis or trans tetrahydrocannabinol, and their optical isomers
- 6 cis or trans tetrahydrocannabinol, and their optical isomers
- 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: March 18, 2003.

John B. Brown III,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA-206F]

RIN 1117-AA55

Exemption From Control of Certain Industrial Products and Materials Derived From the Cannabis Plant

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is adopting as final an interim rule exempting from control (*i.e.*, exempting from all provisions of the Controlled Substances Act (CSA)) certain items derived from the cannabis plant and containing tetrahydrocannabinols (THC). Specifically, the interim rule exempted THC-containing industrial products,

processed plant materials used to make such products, and animal feed mixtures, provided they are not used, or intended for use, for human consumption (and therefore cannot cause THC to enter the human body).

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

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

This final rule revises the DEA regulations to add a provision exempting from CSA control certain THC-containing industrial products, processed plant materials used to make such products, and animal feed mixtures, provided such products, materials, and feed mixtures are made from those portions of the cannabis plant that are excluded from the definition of marijuana and are not used, or intended for use, for human consumption. Among the types of industrial products that are exempted as a result of this final rule are: (i) Paper, rope, and clothing made from cannabis stalks; (ii) processed cannabis plant materials used for industrial purposes, such as fiber retted from cannabis stalks for use in manufacturing textiles or rope; (iii) animal feed mixtures that contain sterilized cannabis seeds and other ingredients (not derived from the cannabis plant) in a formulation designed, marketed, and distributed for animal (nonhuman) consumption; and (iv) personal care products that contain oil from sterilized cannabis seeds, such as shampoos, soaps, and body lotions (provided that using such personal care products does not cause THC to enter the human body).

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. In addition, the Attorney General is authorized to exempt, by regulation, any compound, mixture, or preparation containing any controlled substance from the

application of all or any part of the CSA if he finds such compound, mixture, or preparation meets the requirements of section 811(g)(3). 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 DEA Exempting From Control Certain THC-Containing Substances Not Intended for Human Consumption?

Without the exemptions made by the interim rule, which are adopted as final in this rule, a wide variety of legitimate industrial products derived from portions of the cannabis plant would be considered schedule I controlled substances. For example, paper, rope, and clothing (made using fiber from cannabis stalks) and industrial solvents, lubricants, and bird seed mixtures (made using sterilized cannabis seeds or oil from such seeds) would, in the absence of the interim rule, be considered schedule I controlled substances if they contained THC. If such products were considered schedule I controlled substances, their use would be severely restricted.¹ Under the interim rule, however, which DEA is adopting as final here, DEA exempted such legitimate industrial products from control, provided they are not used, or intended for use, for human consumption. As explained below, DEA believes this approach protects the public welfare within the meaning of the CSA while striking a fair balance between the plain language of the Act and the intent of Congress under prior marijuana legislation.

THC is an hallucinogenic substance with a high potential for abuse. Congress recognized this fact by placing it in schedule I of the CSA. Because of this, there are only two ways that THC may lawfully enter a person's body: (1) If the THC is contained in a drug product that has been approved by the Food and Drug Administration (FDA) as being safe and effective for human use;²

¹ The CSA and DEA regulations permit industrial use of schedule I controlled substances, but only under strictly regulated conditions.

² 21 U.S.C. 331, 355, 811(b), 812(b). At present, Marinol® is the only THC-containing drug product that has been approved for marketing by FDA. Marinol® is the brand name of a product containing synthetic dronabinol (a form of THC) in sesame oil and encapsulated in soft gelatin capsules that 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. Because Marinol® is the only THC-containing drug approved by FDA, it is the only THC-containing substance listed in a schedule other than schedule

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