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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 I

AGENCY: 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.

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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]

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).

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[1] For example, Merriam-Webster's Collegiate Dictionary (10th ed. 1999) defines ''THC'' as ''a physiologically active chemical $C_{21}H_{30}O_2$ 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 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 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 rule] that the APA requires it to comply with notice and comment'').

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

[10] Legislative 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).

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 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 (''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]

[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 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.

[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 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

[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.

[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 manufacture 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.

[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.

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:

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.)

* * * * *

Dated: March 18, 2003.

John B. Brown III,

Acting Administrator.

[FR Doc. 03–6804 Filed 3–20–03; 8:45 am]

BILLING CODE 4410–09–P

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: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537; Telephone: (202) 307–7183.

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

Continued

or (2) if an experimental drug containing THC is provided to a research subject in clinical research that has been approved by FDA and conducted by a researcher registered with DEA.[3] Disallowing human consumption of schedule I controlled substances except in the foregoing limited circumstances is an absolute necessity to conform with the CSA and protect the public welfare within the meaning of the Act.[4]

Where, however, a schedule I controlled substance is contained in a product not used for human consumption, the CSA provides DEA with discretionary authority to issue regulations exempting such product from control.[5] DEA has carefully considered whether it is appropriate to exercise this discretionary authority when it comes to industrial ''hemp'' products (*i.e.,* products made from portions of the cannabis plant excluded from the CSA definition of marijuana). The text of the CSA and its legislative history make no mention of industrial uses of the cannabis plant. However, DEA has taken into account that, under prior legislation (the Marihuana Tax Act of 1937), Congress intended to permit the use of certain cannabis-derived industrial products. The Senate Report accompanying the 1937 Act stated:

> The [cannabis] plant * * * has many industrial uses. From the mature stalks, fiber is produced which in turn is manufactured into twine, and other fiber products. From the seeds, oil is extracted which is used in the manufacture of such products as paint, varnish, linoleum, and soap. From hempseed cake, the residue of the seed after the oil has been extracted, cattle feed and fertilizer are manufactured. In addition, the seed is used as a special feed for pigeons.

S. Rep. No. 900, 75th Cong., 1st Sess., at 2–3 (1937). DEA recognizes that the intent of Congress in 1937 to allow the foregoing industrial ''hemp'' products is no longer controlling because the CSA (enacted in 1970) repealed and superseded the 1937 Marihuana Tax Act. DEA further recognizes that the allowance that Congress made for such products under the now-rescinded Marihuana Tax Act was based on a 1937 assumption (now refuted) that such products contained none of the psychoactive drug now known as THC. (In contrast, when Congress enacted the CSA in 1970, it expressly declared that anything containing THC is a schedule I controlled substance.)[6] Still, for the reasons provided below, DEA believes it is an appropriate exercise of the Administrator's discretionary authority under the CSA to issue an exemption allowing the legitimate industrial uses of ''hemp'' that were allowed under the 1937 Act. At the same time, DEA has been careful to ensure that this exemption comports with the CSA by maintaining the rule that no humans may lawfully take THC into their bodies except when they are (i) using an FDA-approved drug product or (ii) the subjects of FDA-authorized research.

DEA may not arbitrarily exempt a controlled substance from application of the CSA. Rather, such an exemption must be based on a provision of the CSA. As cited above, the exemption of certain ''hemp'' products under this final rule is issued pursuant to two CSA provisions: 21 U.S.C. 811(g)(3)(B) and 871(b).

Pursuant to 811(g)(3)(B), the Administrator of DEA may exempt from control ''[a] compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.'' This provision, which was added to the CSA in 1984, was aimed primarily at analytic standards and preparations which are not for use in humans and pose no significant abuse threat by nature of their formulation. It bears emphasis, however, that Congress did not mandate that DEA exempt from control all mixtures and preparations that DEA determines meet the criteria of section 811(g)(3)(B). Rather, as the word ''may'' in the first line of section 811(g)(3) indicates, Congress gave DEA discretionary authority to issue such exemptions.

The DEA regulation that implements section 811(g)(3)(B) is 21 CFR 1308.23. Section 1308.23(a) provides that the Administrator may exempt from control a chemical preparation or mixture containing a controlled substance that is ''intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or other animal'' if it is packaged in such a form or concentration, or with adulterants or denaturants, so that the presence of the controlled substance does not present any significant potential for abuse.

DEA believes that industrial ''hemp'' products such as paper, clothing, and rope, when used for legitimate industrial purposes (not for human consumption) meet the criteria of section 811(g)(3)(B) and § 1308.23. Legitimate use of such products cannot result in THC entering the human body. Moreover, allowing these products to be exempted from CSA control in no way hinders the efficient enforcement of the CSA. Accordingly, DEA believes that these types of industrial products should be exempted from application of the CSA, provided they are not used, or intended for use, for human consumption. For the same reasons, processed cannabis plant materials that cannot readily be converted into any form that can be used for human consumption, and which are used in the production of such legitimate industrial products, are being exempted from control under this final rule.

The use of sterilized cannabis seeds[7] that contain THC in animal feed fails to meet the criteria of section 811(g)(3)(B) and section 1308.23 because this involves the use of a controlled substance (THC) in animals.[8] Nonetheless, pursuant to 21 U.S.C. 871(b), DEA believes it is appropriate to exempt from application of the CSA animal feed mixtures containing such seeds, provided the seeds are mixed with other ingredients that are not derived from the cannabis plant in a formulation designed, marketed and distributed for animal consumption (not for use in humans). 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. It should be underscored that section 871(b) is not a catchall provision that can be used to justify any exemption. For the following

I. DEA recently transferred Marinol® from schedule II to schedule III, thereby lessening the CSA regulatory requirements governing its use as medicine. See 64 FR 35928 (1999).

[3] 21 U.S.C. 823(f); 21 CFR 5.10(a)(9), 1301.18, 1301.32.

[4] In enacting the CSA, Congress stated: ''The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.'' 21 U.S.C. 801(2).

[5] See 21 U.S.C. 811(g)(3); see also 21 U.S.C. 871(b) (providing discretionary authority to DEA Administrator to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under [the CSA].'').

[6] A detailed comparison of the 1937 Marihuana Tax Act and the CSA is provided in the October 9, 2001 interpretive rule. 66 FR at 51530–51531.

[7] Unless otherwise indicated, all references in this document to ''cannabis seeds'' or '' 'hemp' seeds'' refer to sterilized seeds (incapable of germination). In contrast to sterilized cannabis seeds, unsterilized cannabis seeds fit within the CSA definition of marijuana and are not exempted from control under this interim rule.

[8] If, however, the ''hemp'' seeds used in animal feed are sterilized cannabis seeds that contain no THC, such seeds are not a controlled substance. Under such circumstances, there is no need to exempt such seeds from control.

reasons, however, DEA believes that the use of sterilized cannabis seeds in animal feed mixtures is a unique situation that warrants an exemption pursuant to section 871(b).

As stated above and in the interpretive rule, the legislative history of the 1937 Marihuana Tax Act reveals that Congress expressly contemplated allowing ''hemp'' animal feed. The 1937 Congress categorized such use of ''hemp'' as a legitimate ''industrial'' use. It is true that the intent of the 1937 Congress is no longer controlling since the CSA repealed the 1937 Act and declared anything containing THC to be a schedule I controlled substance. However, because neither the text nor the legislative history of the CSA addresses the legality of using sterilized cannabis seeds in animal feed, or the possibility that such seeds might contain THC, what was viewed under the 1937 Act as ''legitimate industrial use'' of such seeds in animal feed continued uninterrupted following the enactment of the CSA in 1970.

The historical lack of federal regulation of some THC-containing products (whether based on differences between prior law and the CSA, lack of awareness of the THC content of such product, or other considerations) does not—by itself—justify exempting such product from control under the CSA. DEA remains obligated to apply the provisions of the CSA to all controlled substances absent a statutory basis to exempt a particular substance from control. However, with respect to animal feed mixtures containing sterilized cannabis seeds, additional factors (combined with Congress' express desire under prior legislation to allow such products) justify an exemption pursuant to section 871(b). The presence of a controlled substance in animal feed poses less potential for abuse than in a product intended for human use and does not entail the administration of THC to humans. Moreover, when sterilized cannabis seeds are mixed with other animal feed ingredients and not designed, marketed, or distributed for human use, there is minimal risk that they will be converted into a product used for human consumption. Therefore, such legitimate use in animal feed mixtures poses no significant danger to the public welfare. Accordingly, given the unique circumstances and history surrounding the use of sterilized cannabis seeds in animal feed, DEA believes that it comports with the CSA to continue to treat such activity as a legitimate industrial use—not subject to CSA control—provided the foregoing conditions are met.

How Is ''Human Consumption'' Defined Under This Rule?

Under this final rule, a material, compound, mixture, or preparation containing THC will be considered ''used for human consumption'' (and therefore not exempted from control) if it is: (i) Ingested orally or (ii) applied by any means such that THC enters the human body. A material, compound, mixture, or preparation containing THC will be considered ''intended for use for human consumption'' and, therefore, not exempted from control if it is: (i) Designed by the manufacturer for human consumption; (ii) marketed for human consumption; or (iii) distributed, exported, or imported with the intent that it be used for human consumption.

In any legal proceeding arising under the CSA, the burden of going forward with the evidence that a material, compound, mixture, or preparation containing THC is exempt from control pursuant to this rule shall be upon the person claiming such exemption. 21 U.S.C. 885(a)(1). In order to meet this burden with respect to a product or processed plant material that has not been expressly exempted from control by the Administrator pursuant to 21 CFR 1308.23 (as explained below under the heading ''What Is the Control Status of Personal Care Products Made from 'Hemp'?''), the person claiming the exemption must present rigorous scientific evidence, including well-documented scientific studies by experts trained and qualified to evaluate the effects of drugs on humans.

How Are ''Processed Plant Material'' and ''Animal Feed Mixture'' Defined Under This Rule?

Under this final rule, any portion of the cannabis plant excluded from the CSA definition of marijuana will be considered ''processed plant material'' if it has been subject to industrial processes, or mixed with other ingredients, such that it cannot readily be converted into any form that can be used for human consumption. For example, fiber that has been separated from the mature stalks by retting for use in textiles is considered processed plant material, which is exempted from control, provided it is not used, or intended for use, for human consumption. In comparison, mature stalks that have merely been cut down and collected do not fit within the definition of ''processed plant material'' and, therefore, are not exempted from control. As another example, if a shampoo contains oil derived from sterilized cannabis seeds, one would expect that, as part of the production of the shampoo, the oil was subject to industrial processes and mixed with other ingredients such that, even if some THC remains in the finished product, the shampoo cannot readily be converted into a product that can be consumed by humans. Under such circumstances, the product is exempted from control under this final rule. In comparison, a personal care product that consists solely of oil derived from cannabis seeds does not meet the definition of ''processed plant material'' under this final rule and, therefore, is not exempted from control.

''Animal feed mixture'' is defined under this final rule to mean sterilized cannabis seeds mixed with other ingredients in a formulation that is designed, marketed, and distributed for animal consumption (and not for human consumption). For example, sterilized cannabis seeds mixed with seeds from other plants and for sale in pet stores fit within the definition of ''animal feed mixture'' and are exempted from control under this final rule provided the feed mixture is not used, or intended for use, for human consumption. (In contrast, a container of pure sterilized cannabis seeds—mixed with no other ingredients—does not meet the definition of ''animal feed mixture'' under this final rule and, therefore, is not exempted from control.)

Which ''Hemp'' Products Are Exempted From Control Under This Rule?

It is impossible to list every potential product that might be made from portions of the cannabis plant excluded from the definition of marijuana. Therefore, DEA cannot provide an exhaustive list of ''hemp'' products that are exempted from control under this final rule. Nonetheless, in order to provide some guidance to the public, the following are some of the more common ''hemp'' products that are exempted (noncontrolled) under this final rule, provided they are not used, or intended for use, for human consumption: paper, rope, and clothing made from fiber derived from cannabis stalks, industrial solvents made with oil from cannabis seeds, and bird seed containing sterilized cannabis seed mixed with seeds from other plants (or other ingredients not derived from the cannabis plant). Personal care products (such as lotions and shampoos) made with oil from cannabis seeds are also generally exempted, as explained below.

Which ''Hemp'' Products Are Not Exempted From Control Under This Rule?

Other than those substances that fit within the exemption being issued in

this final rule, all other portions of the cannabis plant, and products made therefrom, that contain any amount of THC are schedule I controlled substances.

Again, because one cannot list every conceivable ''hemp'' product, it is impossible to examine here every ''hemp'' product for a determination of whether such product is used, or intended for use, for human consumption within the meaning of this final rule. Therefore, this document contains no exhaustive list of ''hemp'' products that are not exempted from control under this final rule. Nonetheless, to provide some guidance, the following are some of the ''hemp'' products that are not exempted from control under this final rule (and therefore remain controlled substances) if they contain THC: any food or beverage (such as pasta, tortilla chips, candy bars, nutritional bars, salad dressings, sauces, cheese, ice cream, and beer) or dietary supplement.

What Is the Control Status of Personal Care Products Made From ''Hemp''?

DEA has not conducted chemical analyses of all of the many and varied personal care products that are marketed in the United States, such as lotions, moisturizers, soaps, or shampoos that contain oil from sterilized cannabis seeds. Indeed, it appears that there is no reliable source of information on these products. Accordingly, DEA does not know whether every personal care product that is labeled a ''hemp'' product necessarily was made using portions of the cannabis plant, and if so, whether such portions of the plant are those excluded from the definition of marijuana. Even if one assumes that a product that says ''hemp'' on the label was made using cannabis seeds or other portions of the plant, one cannot automatically infer, without conducting chemical analysis, that the product contains THC.[9] Assuming, however, that a ''hemp'' product does contain THC, and assuming further that such product is marketed for personal care (*e.g.*, body lotion or shampoo), the question remains whether the use of the product results in THC entering the human body. DEA is unaware of any scientific evidence that definitively answers this question. Therefore, DEA cannot state, as a general matter, whether ''hemp'' personal care products are exempted from control under this final rule. Nonetheless, given the information currently available, DEA will assume, unless and until it receives evidence to the contrary, that most personal care products do not cause THC to enter the human body and, therefore, are exempted under this final rule. For example, DEA assumes at this time that lotions, moisturizers, soaps, and shampoos that contain oil from sterilized cannabis seeds meet the criteria for exemption under this final rule because they do not cause THC to enter the human body and cannot be readily converted for human consumption. However, if a personal care ''hemp'' product is formulated and/or designed to be used in a way that allows THC to enter the human body, such product is not exempted from control under this final rule.

Again, it must be emphasized that, although DEA believes that most personal care ''hemp'' products currently marketed in the United States meet the criteria for exemption under this final rule, it is not possible for DEA to provide an exhaustive list of every such product and to state whether such product is exempted. Should manufacturers, distributors, or importers of ''hemp'' personal care products wish to have their products expressly exempted from control, they should take steps to determine whether such products contain THC and, if they do contain THC, whether use of the products results in THC entering the human body. Any such manufacturer, distributor, or importer who believes that its product satisfies the criteria for exemption under this final rule may request that DEA expressly declare such product exempted from control by submitting to DEA an application for an exemption, together with appropriate scientific data, in accordance with the procedures set forth in 21 CFR 1308.23(b) and (c).

A manufacturer, distributor, or importer of a ''hemp'' product that meets the criteria for exemption under this final rule need not obtain an express exemption from DEA in order to continue to handle such product. Rather, this is a voluntary procedure. DEA leaves it to the individual manufacturer, distributor, or importer to decide whether there is sufficient uncertainty about its product to seek an express exemption from DEA. However, any person who continues to handle a ''hemp'' product that does not meet the criteria for an exemption under this final rule is subject to liability under the CSA.

What Is the Legal Status of ''Hemp'' Products That Contain No THC?

Any portion of the cannabis plant, or any product made therefrom, or any product that is marketed as a ''hemp'' product, that is both excluded from the definition of marijuana and contains no THC—natural or synthetic—(nor any other controlled substance) is not a controlled substance. Accordingly, such substances need not be exempted from control under this final rule, since they are, by definition, noncontrolled.

What Is the Justification for Issuing the Exemptions Under This Rule?

DEA believes it is both necessary for the most effective enforcement of the CSA and consistent with the public interest to allow the exemptions contained in this rule. Otherwise, as provided in the CSA and DEA regulations, all products containing any amount of THC are schedule I controlled substances. In other words, in the absence of this final rule, legitimate industrial ''hemp'' products such as paper, rope, clothing, and animal feed mixtures would be schedule I controlled substances if they contain THC. Thus, without the exemptions that are being finalized in this rule, anyone who sought to import such products for legitimate industrial uses would need to obtain a DEA registration and an import permit. 21 U.S.C. 952(a)(2), 957(a). Likewise, distributors of such products would need a DEA registration and would be required to utilize DEA order forms and maintain strict records of all transactions. 21 U.S.C. 822(a)(1), 827(a), 828(a). DEA believes that such regulatory requirements are unnecessary to protect the public welfare and achieve the goals of the CSA, provided such products are not used, or intended for use, for human consumption. Furthermore, DEA believes that it would not be an appropriate prioritization of limited agency resources to take on the responsibility of regulating these products as schedule I controlled substances when they are not being used for human consumption. Therefore, as long as there is no possibility that humans will consume THC by using something other than an FDA-approved drug product or a product that the FDA has authorized for clinical research, DEA believes that it is consistent with the purposes and structure of the CSA to exempt industrial ''hemp'' products, processed plant materials, and animal feed mixtures in the manner specified in this final rule.

[9] Any product that (i) is made from portions of the cannabis plant excluded from the CSA definition of marijuana and (ii) contains no THC (nor any other controlled substance) is not a controlled substance.

What Are the Registration Requirements for Handlers of ''Hemp'' Products Under This Final Rule?

In light of the exemptions provided under this rule, the following registration requirements should be considered:

Who must obtain a registration—Persons who wish to manufacture or distribute any THC-containing product or plant material that is not exempted from control under this rule must apply for the corresponding registration to handle a schedule I controlled substance. Absent such registration, it is unlawful to manufacture, distribute, or dispense, import, or export any such product or plant material. 21 U.S.C. 822(b), 841(a)(1), 957(a), 960(a). The circumstances under which DEA may grant registrations to handle schedule I controlled substances are limited, as set forth in 21 U.S.C. 823.

In addition, no person may cultivate the cannabis plant for any purpose except when expressly registered with DEA to do so. This has always been the case since the enactment of the CSA. 21 U.S.C. 822(b), 823(a); 21 CFR Part 1301; *see New Hampshire Hemp Council, Inc.* v. *Marshall, 203* F.3d 1 (1st Cir. 2000). Further, the CSA prohibits the importation of schedule I controlled substances except as authorized by 21 U.S.C. 952(a)(2). Similarly, the CSA prohibits the exportation of schedule I nonnarcotic controlled substances except as authorized by 21 U.S.C. 953(c).

Who need not obtain a registration—Persons who import and distribute ''hemp'' products and processed cannabis plant material that are exempted from control under this final rule are not subject to any of the CSA requirements, including the requirement of registration. For example, a person who imports ''hemp'' clothing is not considered to be importing a controlled substance and is, therefore, not subject to any of the CSA requirements. Similarly, a person who has imported into the United States processed cannabis plant material that is exempted under this rule (such as retted fiber) and converts such material into an exempted ''hemp'' product (such as clothing) is not considered to be manufacturing a controlled substance and, therefore, need not obtain a controlled substance manufacturing registration.

It is worth repeating here that, if a product marketed as a ''hemp'' product actually contains no THC (or any other controlled substance), it is noncontrolled and handlers of the product are not subject to any of the CSA provisions, such as the registration requirement.

Comments That DEA Received in Response to the Interim Rule

Following publication of the interim 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. In accordance with the Administrative Procedure Act, DEA carefully considered all of the comments it received.

Most of the comments that DEA received relate to both of the rules that DEA published on October 9, 2001: (i) DEA 205 (66 FR 51535), a proposed rule, which proposed to clarify that the listing of THC includes both natural and synthetic THC and (ii) DEA 206 (66 FR 51539), an interim rule, which exempted certain THC-containing products and plant materials from control. Those comments that DEA received which pertain primarily to the interim rule are addressed here. Those comments which pertain primarily to the proposed rule are addressed in the final DEA 205 rule, which appears in a separate **Federal Register** document that immediately precedes 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. The issues raised overlapped to a large extent as many persons submitted form letters or signed petitions written by groups which themselves submitted lengthy comments. In this document, together with the final proposed rule, DEA has addressed all the major issues raised by the commenters. Some of these issues are addressed above in the text that precedes this section. The remaining issues are addressed below.

Comments Regarding Which Products To Exempt From Control

None of the commenters objected to the basic purpose of this rule: To exempt from control certain THC-containing industrial products and animal feed mixtures made from ''hemp'' (portions of the cannabis plant excluded from the definition of marijuana). To the contrary, all the commenters who expressed an opinion on this particular issue agreed with these exemptions.[10] However, many commenters said that DEA should go further by also exempting ''hemp'' food and beverage products that contain THC. DEA declined to adopt this suggestion for the reasons provided herein.

Those commenters who requested that DEA exempt THC-containing ''hemp'' food and beverage products made two main claims in support of this request: (i) That ''hemp'' foods and beverages contain only minimal amounts of THC, which, they asserted, cannot cause any psychoactive effects; and (ii) that the oil from ''hemp'' seeds (sterilized cannabis seeds) provides nutritional value and is a safe food ingredient.[11]

As to the issue of THC content, many of the comments appeared to be asking DEA simply to assume that the placement of the word ''hemp'' on the label of a food or beverage product automatically means that the product contains a certain low amount of THC. In fact, the existence of the word ''hemp'' on the label of a food container provides no definitive proof of its contents. The FDA cannot and does not evaluate the contents of every food product sold in the United States. Since there is no reliable information about the contents of all foods and beverages marketed as ''hemp'' products, it cannot automatically be assumed that all such products will never cause a psychoactive effect or a positive drug test for THC.

One scientific study published in 1997 examined ''hemp'' salad oil (containing oil from cannabis seeds) sold in ''hemp shops'' and health food stores in Switzerland. The authors of the study stated that all the human subjects who ate the cannabis seed oil reported THC-specific psychotropic symptoms and had urine samples positive for THC.[12] In citing this study, DEA is not

[10] Some commenters were under the mistaken impression that DEA failed to exempt any products from control. These commenters asked DEA to exempt what DEA had already exempted under the interim rule. For example, several commenters objected to DEA's supposed failure to exempt ''hemp'' clothing and paper, even though the interim rule stated repeatedly that such products were being exempted.

[11] Some commenters also expressed concern about the economic impact of disallowing THC-containing ''hemp'' food and beverage products. This issue is addressed in the final 205 rule, in the regulatory certifications.

[12] T. Lehman, Institute of Pharmacy, University of Bern, *et al.,* Excretion of Cannabinoids in Urine after Ingestion of Cannabis Seed Oil, Journal of Analytical Toxicology, vol. 21 (September 1997).

suggesting that all ''hemp'' food and beverage products cause psychoactive effects. Rather, DEA mentions this study in response to the assertions made by some commenters that eating ''hemp'' foods cannot possibly cause psychoactive effects.[13]

Attached to one of the comments was another study, which was also financed by various ''hemp'' companies. This study, entitled ''Assessment of Exposure to and Human Health Risk from THC and other cannabinoids in hemp foods,'' reached similar conclusions about the reduced levels of THC in currently marketed ''hemp'' foods and the diminished likelihood of testing positive for THC when consuming such products.

As for the comments claiming that ''hemp'' foods provide essential nutrients and are safe to eat, it is not DEA's role under the CSA to assess the nutritional value or safety of foods.[14] Regardless of whether the oil from cannabis seeds contains certain nutrients,[15] the CSA does not provide for DEA to exempt food products that contain THC. As explained above and in the text accompanying the interim rule, the CSA prohibits human consumption of ''any quantity'' of a schedule I hallucinogenic substance outside of an FDA-approved product or FDA-approved research. Other than drugs that have been approved by the FDA for prescription use, or drugs that may be lawfully sold over the counter without a prescription, DEA may not exempt controlled substances to allow them to be used for human consumption—even in the case of products that supposedly contain only ''trace amounts'' of a controlled substance. 21 U.S.C. 811(g). Thus, DEA may not, as some commenters proposed, pick an arbitrary cutoff line allowing a certain percentage of THC in foods and beverages. Moreover, notwithstanding the statutory prohibition, DEA believes it would be inappropriate to attempt to establish an acceptable level of schedule I hallucinogens in food products. For example, it would not be appropriate to allow food products to contain ''trace amounts'' of such other schedule I hallucinogens as LSD or MDMA (''ecstasy''). Finding that it is contrary to the public welfare to allow human consumption of ''any quantity'' of schedule I hallucinogens, Congress did not give DEA the authority to determine what constitutes a ''safe amount'' of such drugs in food.[16]

Accordingly, DEA has limited the exemptions provided in this final rule to those cannabis-derived ''hemp'' products that do not cause THC to enter the human body.

Comments Regarding Testing Methods To Evaluate THC Content of Foods and Beverages

Many commenters asked the agency to indicate how it will determine whether a food or beverage product contains THC. Under federal law, it is legally sufficient to demonstrate a violation of the CSA based on the presence of any measurable amount of a prohibited controlled substance.[17] Thus, the questions raised by the commenters are: ''What testing methods will DEA utilize to determine whether a food product contains a measurable amount of THC and how sensitive are such methods?''

DEA will utilize testing assays or protocols used in standard analytical laboratories that have demonstrated valid and reliable sensitivity for the measurements of THC.[18] The methodology, level of sensitivity, and degree of testing accuracy in the fields of analytical and forensic chemistry have evolved since the first discovery of THC in the 1960s. A variety of analytical equipment, testing methodologies, and protocols are described in the published scientific literature.[19] Such methods may include (but are not limited to) gas chromatography, liquid chromatography, and mass spectrometry analyses. DEA has not, and will not, utilize any one method to the exclusion of others.[20]

The lower limit of detectability of these assays can vary according to equipment, methodologies, and the form of the sample. Nonetheless, using currently available analytical methodologies and extraction procedures, it is reasonable to reproducibly and accurately detect THC at or below 1 part per million in cannabis bulk materials or products. Should more sensitive assays and analytical techniques be developed in the future, DEA will refine its testing methods accordingly.

Some companies that handle ''hemp'' food products have asked DEA whether the agency would test the companies' products for THC content. It is not

[13] In a later study, financed by various ''hemp'' companies, human subjects were given oil from cannabis seeds containing lower doses of THC than in the Lehman study. G. Leson, *et al.,* Evaluating the Impact of Hemp Food Consumption on Workplace Drug Tests, Journal of Analytic Toxicology, vol. 25 (November/December 2001). The authors of this study reported that ingestion of cannabis seed oil containing these lower doses of THC resulted in little or no positive screening for THC, depending on the amount of THC consumed and the sensitivity of the urine testing. Companies who financed this study assert that the lower THC content given to the subjects of this study is commensurate with the current methods employed by these companies for cleaning the cannabis seeds before removing the oil from them for use in food products.

[14] In the context of the CSA, the public ''safety'' (and DEA's role therein) is implicated by the use of controlled substances for other than a legitimate medical purpose or in any other manner not authorized by the CSA.

[15] Although this rule is not a food safety measure, because DEA received so many comments regarding this issue, some members of the public may be interested in the following information. Under the Federal Food, Drug, and Cosmetic Act, a substance that is added to food is not subject to the requirement of premarket approval if its safety is generally recognized among qualified scientific experts under the conditions of its intended use. 21 U.S.C. 321(s). A substance added to a food may be considered ''generally recognized as safe'' (GRAS) through experience based on ''common use in food,'' which requires a substantial history of consumption for food use by a significant number of consumers. 21 CFR 170.3(f), (h); 21 CFR 170.30. The FDA evaluated an industry submission claiming GRAS status for certain food uses of ''hempseed oil'' and expressly stated that it did not believe the submission provided a sufficient basis to classify ''hempseed oil'' as GRAS through experience based on common use in food. *See* FDA Center for Food Safety & Applied Nutrition, Office of Premarket Approval, Agency Response Letter, GRAS Notice No. GRN 00035 (August 24, 2000), reproduced at *www.cfsan.fda.gov/rdb/opa-g035.html.* In making this determination, the FDA did not evaluate whether there would be a basis for GRAS status through scientific procedures or whether ''hempseed oil'' would meet the standard for premarket approval as a food additive. *Id.*

[16] To establish a violation of the CSA, the government does not have to prove that the controlled substance in question was of sufficient quantity to produce a psychoactive effect. *United States* v. *Nelson,* 499 F.2d 965 (8th Cir. 1974).

[17] *See, e.g., United States* v. *Holland,* 884 F.2d 354, 357 (8th Cir. 1989), cert. denied, 493 U.S. 997 (1989); *see also* 21 U.S.C. 812(c), schedule I(c) (listing ''any material, compound, mixture, or preparation, which contains any quantity'' of hallucinogenic substances in schedule I).

[18] In this context, ''valid'' means that the technique measures what it is designed to measure, and ''reliable'' means that the technique can be replicated by other laboratories.

[19] *See, e.g.,* M.V. Doig & R. Andela, *Analysis of pharmacologically active cannabinoids by GC–MS,* Chromatographia 52 (Supp.): S101–S102 (2000); P.D. Felgate & A.C. Dinan, *The determination of delta-9-tetrahydrocannabinol and 11-Nor-9-carboxy-delta-9-tetrahydrocannabinol in whole blood using solvent extraction combined with polar solid-phase extraction,* Journal of Analytical Toxicology 24:127–132 (2000); K. Ndjoko, *et al., Analysis of cannabinoids by liquid chromatography-thermospray mass spectrometry* and liquid chromatography-tandem mass spectrometry, Chromatographia 47:72–76 (1998); B.J. Gudzinowicz & M.J. Gudzinowicz, *Analysis of drugs and metabolites by gas chromatography-mass spectrometry,* Volume 7: Natural, pyrolytic, and metabolic products of tobacco and marijuana, NY: Marcel Dekker, Inc. (1980).

[20] What constitutes the appropriate method of testing may vary depending on the circumstances. In any criminal prosecution, civil or administrative action, or other legal proceeding arising under the CSA, where the government must prove the presence of a controlled substance, the government may do so by the introduction of any evidence sufficient under law to prove such fact. *See, e.g., United States* v. *Bryce,* 208 F.3d 346, 352–354 (2d Cir. 2000).

within DEA's authority to serve as such a testing laboratory for private entities. Nor would it be appropriate for DEA to certify laboratories for these analyses. Manufacturers and distributors of ''hemp'' food and beverage products may, of course, conduct their own testing to determine to their own satisfaction that their products contain no THC. However, they are under no obligation to do so. Whether or not they conduct such testing, the law remains the same: if a food or beverage product contains any measurable amount of THC, it is an illegal schedule I controlled substance; if it contains no THC, it is a legal, noncontrolled substance.

Comments Regarding Drug Screening

Several commenters asserted that, in deciding whether or not to exempt THC-containing food and beverage products, DEA should not concern itself with the possibility that persons who eat such products then undergo drug screening might test positive for THC. Some of these commenters suggested that ''hemp'' food and beverage manufacturers have taken steps to ensure that the amount of THC in their products is low enough to avoid causing a positive drug screen. Given these comments, it must be emphasized that, while effective drug screening in appropriate circumstances is of concern to DEA and was part of the agency's overall consideration, the ultimate decision about which products to exempt from control did not turn on drug testing considerations. Rather, as explained above, DEA exempted certain products to the extent permissible by the CSA and consistent with the public welfare within the meaning of the Act.

Although drug testing was not the basis for the exemptions, in view of the comments about drug testing, it is worth reiterating that there are no uniform standards of what constitutes a ''hemp'' product. It cannot be said that, merely because a product has the word ''hemp'' on the label, it will necessarily contain a certain low amount of THC. Therefore, it cannot automatically be said that a food or beverage product marketed as containing ''hemp'' will never cause a positive drug test for THC. In fact, as noted above, one published scientific study found that eating ''hempseed'' salad oil (of a variety sold in ''hemp shops'' in Switzerland) did cause human research subjects to test positive for THC.

Comments Regarding the Cultivation of Cannabis for Industrial Purposes

Some commenters asserted that the United States should promote the cultivation of cannabis for industrial purposes based on economic and environmental considerations. These commenters seemed to misunderstand the nature of the rules being finalized today. The rules do not impose restrictions on, or even address, the cultivation of cannabis. Rather, as the text accompanying the rules makes clear, the rules clarify which cannabis-derived products are controlled and which are exempted from control.

As stated above, it has always been the case since the enactment of the CSA in 1970 that any person who seeks to lawfully grow cannabis for any purpose (including the production of ''hemp'' for industrial purposes) must obtain a DEA registration. This requirement remains in effect and is not modified by the rules DEA is finalizing today.

Regulatory Certifications

Economic Impact of This Rule

This rule allows economic activity that would otherwise be prohibited. As has now been made clear under the DEA regulations being finalized today, all products that contain any amount of THC are schedule I controlled substances unless they are specifically listed in another schedule or exempted from control. Thus, without the exemptions provided in this final rule, industrial ''hemp'' products such as paper, rope, clothing, and animal feed would be subject to the provisions of the CSA and DEA regulations that govern schedule I controlled substances if they contained THC. The CSA permits the use of schedule I controlled substances for industrial purposes, but only under strictly regulated conditions. By virtue of this rule, however, most industrial ''hemp'' products are exempt from all provisions of the CSA and DEA regulations. Thus, this rule imposes no regulatory restrictions on any economic activities; rather, it removes regulatory restrictions on certain economic activities.

Regulatory Flexibility Act

For the reasons provided in the foregoing paragraph, 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)). Therefore, a final regulatory flexibility analysis is not required for this final rule.

Executive Order 12866

This rule has been drafted and reviewed in accordance with Executive Order 12866, Regulatory Planning and Review, section 1(b), Principles of Regulation. This rule has been determined to be a ''significant regulatory action'' under Executive Order 12866, section 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

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. Accordingly, under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), this is not a major rule as defined in 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 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, the Acting Administrator hereby orders that the interim rule amending title 21 of the Code of Federal Regulations, part 1308, to include new § 1308.35, which was published at 66 FR 51539, on October 9, 2001, is adopted as a final rule without change.

Dated: March 18, 2003.

John B. Brown III,

Acting Administrator.

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