

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

[DEA-206]

RIN 1117-AA55

Exemption From Control of Certain Industrial Products and Materials Derived From the Cannabis Plant**AGENCY:** Drug Enforcement Administration, Justice.**ACTION:** Interim rule and request for comments.

SUMMARY: In a separate document published today in the **Federal Register**, the Drug Enforcement Administration (DEA) issued an interpretive rule stating that under the Controlled Substances Act (CSA) and DEA regulations, any product that contains any amount of tetrahydrocannabinols (THC) is a schedule I controlled substance, even if such product is made from those portions of the cannabis plant that are excluded from the CSA definition of "marihuana." (Hereafter "the interpretive rule".) In view of the interpretive rule, DEA is issuing this interim rule to exempt from control (i.e., exempt from application of the CSA) 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. With respect to those "hemp" products that are not exempted from control under this interim rule, a 120-day grace period is being provided for persons to dispose of existing inventories.

DATES: This interim rule is effective October 9, 2001. Comments must be received by DEA on or before December 10, 2001. If DEA determines based on any comments received that a modification of this interim rule is warranted, such modification will be specified in the final rule.

As set forth in this document, a grace period is being provided for persons to dispose of existing inventories of "hemp" products that are not exempted from control under this interim rule. Any person who, as of October 9, 2001, possesses a THC-containing hemp product not exempted from control under this interim rule has until February 6, 2002 to dispose of such

product in the manner described in this document.

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

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 interim rule exempts 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 interim rule are paper, rope, and clothing. Also exempted are processed plant materials used for industrial purposes, such as fiber retted from cannabis stalks for use in manufacturing textiles or rope. Also exempted are 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. Personal care products made from "hemp" (i.e., made from portions of the cannabis plant excluded from the CSA definition of marijuana), such as shampoos, soaps, and body lotions, are exempted if using them does not cause THC to enter the human body.

With respect to those THC-containing "hemp" products that are not exempted from control under this interim rule, a 120-day grace period is being provided for persons to dispose of existing inventories of such products.

This interim 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 § 811(g)(3). The functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 21 U.S.C. 871(a); 28 CFR 0.100. A detailed explanation of how the foregoing provisions authorize this interim rule is provided in the next section of this document.

Why Is DEA Exempting From Control Certain THC-Containing Substances Not Intended for Human Consumption?

As explained in detail in the interpretive rule, when Congress enacted the CSA in 1970, it carried forward the definition of marijuana from the 1937 Marihuana Tax Act, which expressly excluded certain portions of the cannabis plant. However, Congress also expressly stated in the CSA scheduling provisions that "any material, compound, mixture, or preparation, which contains any quantity of * * * Tetrahydrocannabinols [THC]" is a schedule I controlled substance. Given these provisions, several members of the public have recently asked DEA whether so-called "hemp" products (i.e., products made from portions of the cannabis plant excluded from the definition of marijuana) are controlled if they contain THC. DEA concluded in the interpretive rule that, under the plain language of the CSA, such products are controlled if they contain THC.

The interpretive rule, standing alone, would view as schedule I controlled substances a wide variety of cannabis-derived industrial products that were not subject to regulation under the Marihuana Tax Act.¹ For example, under the interpretive rule (without this interim rule), products such as paper, rope, clothing, industrial solvents and lubricants, and bird seed mixtures made from portions of the cannabis plant excluded from the definition of marijuana would all be considered schedule I controlled substances if they contained THC. As a result, the use of such legitimate industrial products would be severely restricted. (The CSA

¹ Under the Marihuana Tax Act, persons who grew cannabis to make industrial "hemp" products were required to pay an occupational tax; however, the distribution of "hemp" paper, fiber products, and bird seed was exempt from the Act's taxing provisions.

permits industrial use of schedule I controlled substances, but only under strictly regulated conditions.) Under this interim rule, however, DEA is exempting 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 health and safety while striking a fair balance between the plain language of the CSA 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. Consistent therewith, under the interpretive rule, the proposed rule, and this interim rule (viewed together), there are only two ways that THC may lawfully enter a person's body. First, if the person is using a drug product that has been approved by the Food and Drug Administration (FDA) as being safe and effective for human use.² See 21 U.S.C. 331, 355, 811(b), 812(b). Second, if the person is a research subject in clinical research that has been approved by FDA and conducted by a researcher registered with DEA. 21 U.S.C. 823(f); 21 CFR 5.10(a)(9), 1301.18, 1301.32.

In arriving at this interim rule, DEA has taken into account the uses of "hemp" products that were allowed under the Marihuana Tax Act of 1937. The Senate Report that accompanied the 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).

As explained in the interpretive rule, the intent of Congress in 1937 to allow certain industrial uses of "hemp" is no

longer controlling since the CSA repealed the 1937 Act. This is particularly so given that the 1937 Congress assumed that the "hemp" products it was allowing contained none of the psychoactive drug now known as THC, whereas the 1970 Congress expressly declared anything containing THC to be a schedule I controlled substance. Nonetheless, the legitimate industrial uses of "hemp" allowed under the 1937 Act will generally be allowed under this interim rule. At the same time, DEA believes that this interim rule comports with the CSA by ensuring that no humans may lawfully take THC into their bodies except when they are (i) using a drug product that the FDA has approved as being safe and effective or (ii) the subjects of FDA-authorized research conducted by a DEA registrant.

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 noted above, the exemption of certain "hemp" products under this interim 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 § 811(g)(3)(B). Rather, as the word "may" in the first line of § 811(g)(3) indicates, Congress gave DEA discretionary authority to issue such exemptions.

The DEA regulation that implements § 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 § 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 interim rule.

The use of sterilized cannabis seeds³ that contain THC in animal feed fails to meet the criteria of § 811(g)(3)(B) and § 1308.23 because this involves the use of a controlled substance (THC) in animals.⁴ 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 (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 § 871(b) is not a catchall provision that can be used to justify any exemption. For the following 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 § 871(b).

³ 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.

⁴ 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.

² 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 I. DEA recently transferred Marinol® from schedule II to schedule III, thereby lessening the CSA regulatory requirements governing its use as medicine. See 64 Fed. Reg. 35928 (1999).

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 a particular THC-containing product (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 § 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 health and safety. 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 Interim Rule?

Under this interim 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 Interim Rule?

Under this interim 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 contrast, 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 interim rule. (In contrast, a personal care product that consists solely of oil derived from cannabis seeds does not meet the definition of “processed plant material” under this interim rule and, therefore, is not exempted from control.)

“Animal feed mixture” is defined under this interim 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 fits within the definition of “animal feed mixture” and is exempted from control under this interim 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 interim rule and, therefore, is not exempted from control.)

Which “Hemp” Products Are Exempted From Control Under This Interim 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 interim 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 interim rule, provided they are not used, or intended for use, for human consumption: paper, rope, and clothing made from fiber derived from cannabis stalks, and bird seed containing sterilized cannabis seed mixed with seeds from other plants (or other ingredients not derived from the cannabis plant).

Which “Hemp” Products Are Not Exempted From Control Under This Interim Rule?

Other than those substances that fit within the exemption being issued in this interim 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 interim rule. Therefore, this document contains no exhaustive list of "hemp" products that are not exempted from control under this interim rule. Nonetheless, to provide some guidance, the following are some of the "hemp" products that are not exempted from control under this interim 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"?

Personal care "hemp" products (such as lotions, moisturizers, soaps, or shampoos that contain oil from sterilized cannabis seeds) present a more difficult question. DEA has not conducted chemical analyses of all of the many and varied "hemp" products that are marketed in the United States. Accordingly, DEA does not know whether every 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, in fact, made using cannabis seeds or other portions of the plant, one cannot automatically infer (without conducting chemical analysis) that the product contains THC.⁵ 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 definitively answering this question. Therefore, DEA cannot state, as a general matter, whether "hemp" personal care products are exempted from control under this interim 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 interim 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 interim 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 designed to be used in a way that causes THC to enter the human body, the product is not exempted from control.

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 interim 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 interim 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 interim rule need not obtain an express exemption from DEA in order to continue to handle such product. 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 interim rule is subject to liability under the CSA (unless such person is acting to dispose of such product within the 120-day grace period, as specified below).

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 (nor any other controlled substance) is not a controlled substance. Accordingly, such substances need not be exempted from control under this interim rule, since they are, by definition, noncontrolled.

What Is the Justification for Issuing This Rule as an Interim Rule, Which Takes Effect Immediately?

The Administrative Procedure Act (APA) provides that "[g]eneral notice of proposed rule making shall be published in the **Federal Register** * * *

" However, this requirement is not applicable "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). Similarly, the APA requirement that a substantive rule be published in the **Federal Register** at least 30 days before its effective date is inapplicable where the agency finds good cause for having the rule take effect immediately upon publication. 5 U.S.C. 553(d)(3).

In this case, 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 interim rule to become effective immediately. Otherwise, as set forth in the interpretive rule, all products containing any amount of THC are schedule I controlled substances. In other words, as DEA interprets current law (in the absence of this interim rule), "hemp" paper, rope, clothing, and animal feed mixtures are schedule I controlled substances if they contain THC. Thus, without this interim rule, anyone who wishes to import such products (or processed plant materials used to make such products) would need to obtain a DEA registration and an import permit. 21 U.S.C. 952(a)(2), 957(a). Distributors of such products and processed plant materials would also 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). With respect to industrial products and processed plant materials exempted under this interim rule, DEA believes that such regulatory requirements are unnecessary to achieve the goals of the CSA provided such products and plant materials are not used, or intended for use, for human consumption. Furthermore, DEA believes that it would be less than an ideal allocation of agency resources if

⁵ Any product that both is made from portions of the cannabis plant excluded from the CSA definition of marijuana and contains no THC (nor any other controlled substance) is not a controlled substance.

DEA had to take on the responsibility of regulating these products and plant materials 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 public health and safety to immediately exempt industrial "hemp" products, processed plant materials, and animal feed mixtures in the manner specified in this interim rule.

What Are the Registration Requirements for Handlers of "Hemp" Products Under This Interim Rule?

As stated above (and as explained in the interpretive rule), DEA interprets the CSA such that all products containing THC are schedule I controlled substances. This interim rule, however, exempts certain industrial "hemp" products, processed plant materials, and animal feed mixtures from application of the CSA. As a result, the following registration requirements will apply:

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 interim 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). In addition, as has always been the case since the enactment of the CSA, no person may cultivate the cannabis plant for any purpose except when expressly registered with DEA to do so. See 21 U.S.C. 822(b), 823(a); 21 CFR Part 1301; *see also 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 interim rule (when not used, or intended for use, for human consumption) are not subject to any of the CSA requirements, including the

requirement of registration. For example, persons who import "hemp" clothing are not subject to any of the CSA requirements. Similarly, persons who obtain processed cannabis plant material that is exempted from control under this interim rule may use such plant material to manufacture products that are not used, or intended for use, for human consumption without being subject to any of the CSA requirements. Again, if a product marketed as a "hemp" product actually contains no THC (or any other controlled substance), it is noncontrolled and not subject to any of the CSA provisions.

Grace Period for Persons With Existing Inventories of THC-Containing Products Not Exempted From Control

It seems likely that, upon publication of this rule, some manufacturers and distributors of THC-containing "hemp" products will have in their possession existing inventories of such products that will be considered controlled under the interpretive rule and the proposed rule and not exempted from control under this interim rule. In fairness to such persons, the following grace period is being provided. Any person who, on the date of publication of this interim rule, possesses a THC-containing "hemp" product not exempted from control under this interim rule will have 120 days (until February 6, 2002) to dispose of such product. However, during this 120-day grace period, no person may use any THC-containing "hemp" product for human consumption (as defined in this interim rule); nor may any person manufacture or distribute such a product with the intent that it be used for human consumption within the United States.

Regulatory Certifications

Economic Impact of This Interim Rule

This interim rule allows economic activity that would otherwise be prohibited. Under DEA's interpretation of current law, all "hemp" products are schedule I controlled substances if they contain THC. Thus, without this interim 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 interim rule, however, such industrial "hemp" products are exempt from all provisions of the CSA and DEA regulations. Thus, this interim 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 Administrator hereby certifies that this interim 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, an initial regulatory flexibility analysis is not required for this interim rule.

Executive Order 12866

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

Executive Order 13132

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

Executive Order 12988—Civil Justice Reform

This interim 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 interim 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 interim 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 interim rule 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 interim rule. However, a copy of this interim rule is being submitted to each House of the Congress and to the Comptroller General in accordance with SBREFA (5 U.S.C. 801).

Paperwork Reduction Act of 1995

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

Plain Language

In writing this interim rule, DEA has attempted to use plain language in an easy-to-read manner, consistent with the June 1, 1998, directive of the President. See 63 FR 31885. If you have any suggestions to make this document easier to understand, call or write Patricia Good, Chief, Liaison and Policy Section, Office of Diversion Control, Washington, DC 20537; telephone: (202) 307-7297.

List of Subjects in 21 CFR Part 1308

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

Interim Rule

Pursuant to the authority vested in the Attorney General under sections 201, 202, and 501(b) of the CSA (21 U.S.C. 811, 812, and 871(b)), delegated to the Administrator pursuant to section 501(a) (21 U.S.C. 871(a)) and as specified in 28 CFR 0.100, the 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. A new undesignated center heading and § 1308.35 are added to read as follows:

EXEMPT CANNABIS PLANT MATERIAL, AND PRODUCTS MADE THEREFROM, THAT CONTAIN TETRAHYDROCANNABINOLS

§ 1308.35 Exemption of certain cannabis plant material, and products made therefrom, that contain tetrahydrocannabinols.

(a) Any processed plant material or animal feed mixture containing any amount of tetrahydrocannabinols (THC) that is both:

(1) Made from any portion of a plant of the genus *Cannabis* excluded from the definition of marijuana under the Act [i.e., the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination] and

(2) Not used, or intended for use, for human consumption, has been exempted by the Administrator from the application of the Act and this chapter.

(b) As used in this section, the following terms shall have the meanings specified:

(1) The term *processed plant material* means cannabis plant material that 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.

(2) The term *animal feed mixture* means sterilized cannabis seeds mixed with other ingredients (not derived from the cannabis plant) in a formulation that is designed, marketed, and distributed for animal consumption (and not for human consumption).

(3) The term *used for human consumption* means either:

(i) Ingested orally or

(ii) Applied by any means such that THC enters the human body.

(4) The term *intended for use for human consumption* means any of the following:

(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.

(c) In any proceeding arising under the Act or this chapter, the burden of going forward with the evidence that a material, compound, mixture, or preparation containing THC is exempt from control pursuant to this section shall be upon the person claiming such exemption, as set forth in section 515(a)(1) of the Act (21 U.S.C. 885(a)(1)). In order to meet this burden with respect to a product or plant material that has not been expressly exempted from control by the Administrator pursuant to § 1308.23, 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.

Dated: October 2, 2001.

Asa Hutchinson,

Administrator.

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