

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.

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(d) * * *

(27) Tetrahydrocannabinols—7370

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

- 1 cis or trans tetrahydrocannabinol, and their optical isomers
- 6 cis or trans tetrahydrocannabinol, and their optical isomers
- 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers

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

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Dated: March 18, 2003.

John B. Brown III,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA-206F]

RIN 1117-AA55

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

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

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

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

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

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

This rule is being issued pursuant to 21 U.S.C. 811, 812, and 871(b). Sections 811 and 812 authorize the Attorney General to establish the schedules in accordance with the CSA and to publish amendments to the schedules in the Code of Federal Regulations, part 1308 of Title 21. Section 871(b) authorizes the Attorney General to promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient enforcement of his functions under the CSA. In addition, the Attorney General is authorized to exempt, by regulation, any compound, mixture, or preparation containing any controlled substance from the

application of all or any part of the CSA if he finds such compound, mixture, or preparation meets the requirements of section 811(g)(3). These functions vested in the Attorney General by the CSA have been delegated to the Administrator and Deputy Administrator of DEA. 21 U.S.C. 871(a); 28 CFR 0.100(b) and 0.104, appendix to subpart R, sec. 12.

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

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

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

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

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

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