

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.<sup>3</sup> 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.<sup>4</sup>

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.<sup>5</sup> 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in 1937 to allow the foregoing industrial “hemp” products is no longer controlling because the CSA (enacted in 1970) repealed and superseded the 1937 Marihuana Tax Act.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products under the now-rescinded Marihuana Tax Act was based on a 1937 assumption (now refuted) that such products contained none of the psychoactive drug now known as THC.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.)<sup>6</sup> 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<sup>7</sup> 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.<sup>8</sup> 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).

<sup>3</sup> 21 U.S.C. 823(f); 21 CFR 5.10(a)(9), 1301.18, 1301.32.

<sup>4</sup> 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).

<sup>5</sup> 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].”).

<sup>6</sup> 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.

<sup>7</sup> 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.

<sup>8</sup> 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.