

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.<sup>9</sup> 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.

<sup>9</sup> 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.