

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).