U. S. Department of Justice
Drug Enforcement Administration

Washington, D.C. 20537

APR 23 2002

The Honorable George Miller
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Miller:

This is in response to the letter dated March 6, 2002, that you and twenty-one of your House colleagues sent to me regarding our interpretation of the Controlled Substances Act (CSA) as it relates to the status of marijuana (cannabis) and "industrial hemp".

"Industrial hemp" is not a term found in federal law. Nor does the term have any specific scientific meaning. Rather, "hemp" or "industrial hemp" are terms used by some to refer to cannabis plants grown to produce fiber for textiles, paper, and oil for industrial products, or seeds and oil for food and beverage products. *Cannabis sativa L.*, whether grown to produce fiber, seeds, and oil or grown for illicit use, is still *Cannabis sativa L.* All cannabis plants contain tetrahydrocannabinols (THC), which is a hallucinogenic substance listed in Schedule I of the Controlled Substances Act (CSA).

While the highest concentrations of THC in cannabis plants are found in the flowering portions, all parts of the plant, including "hemp," have been found to contain THC. The existence of THC in "hemp" is significant because THC is a Schedule I hallucinogenic controlled substance. Federal law prohibits human consumption and possession of Schedule I hallucinogenic controlled substances outside of approved research.

For some time now, DEA has received numerous public inquiries regarding the interpretation of the CSA with respect to certain products made from the cannabis plant. These inquiries have raised the following question: If a product contains THC, but is made from a portion of the cannabis plant that is excluded from the CSA definition of marijuana, is that product a controlled substance? To answer this question, DEA published three rules in the *Federal Register* on October 9, 2001. The complete text of these rules may be found on the DEA website at www.dea.gov/advisories/pa100901.html.

Interpretive Rule

This rule provides DEA's interpretation of the CSA and DEA regulations that any product that contains any amount of tetrahydrocannabinols (THC) is a Schedule I hallucinogenic controlled substance, even if such product is made from those portions of the cannabis plant that are excluded from the CSA definition of "marihuana." *Federal Register Vol. 66, No. 195, Pages 51529-51534.* The plain language of the CSA states that "any material, compound, mixture, or preparation, which contains any quantity of . . . Tetrahydrocannabinols" is a Schedule I hallucinogenic controlled substance, which leads to the conclusion that all products containing any amount of THC are Schedule I hallucinogenic controlled substances. The legislative history supports this conclusion by revealing that Congress wrote the definition of marijuana intending to control all parts of the cannabis plant that were believed to contain THC.

Proposed Rule

Consistent with the interpretive rule, DEA published a proposed rule which revises the wording of the DEA regulations to make clear that the listing of THC in Schedule I refers to both natural and synthetic THC. *Federal Register Vol. 66, No. 195, Pages 51535-51538.* When the CSA was enacted, the implementing regulations did not simply adopt, verbatim, the prior regulations that were expressly limited to synthetic forms of THC. Rather, the word "Tetrahydrocannabinols" was inserted in the regulations at the top of the listing, thereby including all forms of THC (natural and synthetic). The Proposed Rule would make it unequivocal that, under the CSA and DEA regulations, any product that contains any amount of THC (natural or synthetic) is a Schedule I controlled substance, even if such product is made from portions of the cannabis plant that are excluded from the definition of marijuana.

Interim Rule

In view of the interpretive rule, DEA issued an 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. Among the products that are exempt from control under the interim rule are paper, rope, clothing, personal care products, and animal feed mixtures. *Federal Register Vol. 66, No. 195, Pages 51539-51544.*

In summary, THC is a Schedule I hallucinogenic controlled substance. *21 USC 812(c).* The CSA provides that any material, compound, mixture, or preparation which contains any quantity of a Schedule I hallucinogenic substance is a Schedule I hallucinogenic substance, unless such material, compound, mixture, or preparation is expressly exempted from control or listed in another Schedule.

For instance, if sterilized seeds from cannabis plants (sometimes referred to as "hemp seeds") contain THC, they are Schedule I hallucinogenic controlled substances unless they are in a product or formulation that is exempted from control under the DEA regulations. Only those products that are intended for human consumption and cause THC to enter the body are subject to control.

In accordance with the Administrative Procedure Act (APA), the proposed and interim rules were submitted for public comment in the manner described in the October 9, 2001 Federal Register publication. The comment period expired on December 10, 2001. Also in accordance with the APA, DEA will consider the comments received during the comment period and will address those comments upon publication of the final rule in the *Federal Register*.

I was pleased to note that you and your colleagues agree with our reasoning that cannabis products that do not cause THC to enter the body should be exempt from application of the CSA. I must point out that DEA did not change any part of the law. As noted above in the summary of the Interpretive Rule, the CSA clearly declares that any material, compound, mixture, or preparation which contains any amount of THC is a Schedule I hallucinogenic controlled substance. When faced with the fact that all parts of the cannabis plant contain THC, we have no choice but to follow the law. What we tried to do, and I think we have accomplished this, is to strike a balance between products which cause THC to enter the body and those that do not or are not designed, marketed or intended to cause THC to enter the body. Indeed, by exempting these products from application of the CSA, DEA preserved the vast majority of the marketplace for products that are derived from cannabis. Various sources within the cannabis industries declare that the U.S. market for these products is around $25 million annually. I will not endeavor to dispute their assumptions here. I will point out, however, that by their own estimation the cannabis food market accounts for between $2-5 million dollars. We have thereby preserved 80% of the market for cannabis products by limiting the application of the CSA.

Your contention that the Department of Justice shares your position that "legitimate hemp food products are safe and legal under current law" is in error. The rules that were published on October 9, 2002 were reviewed and approved by the Department of Justice under the previous administration and the current administration prior to publication.

Let me also make a few points regarding the arguments put forth by supporters of these products. Namely, the difference between poppy seeds and cannabis seeds, so-called "safe levels" of THC in food, the issue of drug testing, and the notion that cannabis is a panacea for American farmers.

To answer the question regarding poppy seeds, a distinction between poppy seeds and cannabis seeds must be made. Because of distinctions in the law between the control of hallucinogens and the control of opiates, poppy seeds are not banned by the CSA. Opium poppy and opiates are listed as Schedule II controlled substances. *21 USC 812(c)*. The CSA defines "opium poppy" to include all parts of the plant of the species *Papaver somniferum L., except for the seeds*. *21 USC 802(19)*. Thus, poppy seeds are excluded from the definition of opium poppy. While it is true that poppy seeds may contain small amounts of codeine, morphine, and thebaine,

which are Schedule II controlled substances, as set forth in the CSA and DEA regulations, poppy seeds are not considered controlled substances, even if they contain opiates. *21 CFR 1308.12(b)*. In contrast, as previously stated, THC is a Schedule I controlled substance as is any material, compound, mixture, or preparation which contains any quantity of a Schedule I hallucinogenic substance, unless such material, compound, mixture, or preparation is expressly exempted from control or listed in another Schedule.

In addition to the difference between cannabis seeds and poppy seeds under the law, a second distinction can also be made between THC and opiates in the area of drug testing. When someone tests positive in a urine drug screening for opiates, the medical officer can verify whether the positive result was achieved by consuming poppy seeds because of the presence of thebaine – a naturally occurring opioid alkaloid not present in pharmaceutical pain-relief products. There is no such determinative chemical that can differentiate between THC from cannabis food products or smoked marijuana. Low levels of THC in urine could be the result of cannabis food consumption or a smoked marijuana cigarette - there is no way of chemically differentiating the source.

It is important to remember what THC is. THC is a Schedule I hallucinogenic controlled substance. This means it is a psychoactive substance with a high potential for abuse that has not been approved for marketing by the Food and Drug Administration (FDA). DEA, of course, understands that a person may not get high from eating one candy bar with only trace amounts of THC in it. However, there is a published scientific report from the *Journal of Analytical Toxicology* in 1997 of cannabis food products (in particular, "hemp" salad oil) producing a subjectively reported "high" when consumed according to the manufacturers labeled instructions. This oil was produced by a bonafide Swiss Industrial Hemp manufacturer from "hemp" seeds born from marijuana of <0.3% THC. There are numerous other published reports in peer reviewed scientific journals demonstrating THC-positive urine screens resulting from "hemp" food consumption.

Research published in the *Journal of Analytical Toxicology* in 1997 also reveals that consumption of "hemp" seed and "hemp" oil products at the doses recommended by the manufacturer can produce positive urine screens for THC. This has been replicated recently in the laboratory of Dr. Marilyn Huestis at the Intramural Research Laboratories of the National Institute on Drug Abuse (NIDA).

When consumed, THC enters the body and is attracted and binds to fat molecules. THC tends to be stored in the body rather than eliminated or metabolized. THC has a propensity to build up in fat stores and in the membranes of cells, especially nerve cells. There is no known safe lower limit for the consumption of THC, even at low doses. The law does not allow for people to consume "small" amounts of illegal drugs. Nor should it. For example, we don't tell candy bar makers that they can put LSD or heroin in candy bars as long as it is just "trace amounts" of LSD and heroin. Nor would it be practical to have a law that allowed a certain amount of illegal drugs in food products. How could you possibly decide what constitutes an allowable amount of LSD, heroin, or THC in a candy bar? And if you did establish an allowable amount, the taxpayers probably would not want precious law enforcement resources spent conducting tests on every type of drug-containing candy bar being sold in stores to make sure it does not contain more than the allowable amount of illegal drugs.

Neither "hempseed" nor "hempseed" oil have been affirmed by FDA as generally recognized as safe (GRAS) for any food use. A substance that will be added to food is subject to premarket approval by the FDA unless its use is GRAS by qualified experts. The only action by the FDA related to cannabis food additives was in an August 2000 letter addressed to Slavik Dushenkov, Ph.D. of Consolidated Growers and Processors, Inc. Dr. Dushenkov had notified FDA of the view of Consolidated Growers and Producers, Inc. that "hempseed" oil is GRAS through experience based on common use in food, for use in foods as a flavoring agent, adjuvant solvent, vehicle, stabilizer, thickener, emulsifier, or texturizer in food at the minimum amount required to produce the intended effect. In short, the FDA letter objected to the notice on the basis that the information submitted by Dr. Dushenkov did not provide a sufficient basis for a determination that "hempseed" oil is GRAS under the proposed conditions of use. No other submissions regarding the GRAS status of cannabis seeds or oil have been submitted. (see http://www.cfsan.fda.gov/~rdb/opa-g035.html.)

Section 201(s) of the federal Food, Drug, and Cosmetic Act (FDCA) states that a substance that is added to food is not subject to the requirement for premarket approval as a food additive if its safety under intended conditions of use is generally recognized, among qualified experts, through either scientific procedures, or experience based on common use in food prior to 1958. "Common use in food" is defined by FDA regulations (21 CFR 170.3(f)) as a substantial history of consumption for food use by a significant number of consumers. Thus, the fact that something may be used as a food does not demonstrate a common use in food of that substance, nor in itself, is an adequate basis to demonstrate that such use is safe.

The FDA evaluated the information provided by Dr. Dushenkov as well as other data and information that are available to the agency. The FDA determined that the information provided describes some use of "hempseed" oil within one foreign country but does not show that use was sufficiently widespread to demonstrate safety. In fact, the information provided cited a reference that "hempseed" oil rarely was used for food.

Ms. Valerie Vantreese, Department of Agricultural Economics at the University of Kentucky published two papers in 1998 and 2001 regarding the economics of "industrial hemp." Her conclusions were that worldwide production of "hemp" has declined dramatically since the 1960's, falling from over 300,000 metric tons to about 66,500 metric tons in 1998. Production has remained relatively stable since 1998. The world market price for "hemp" fiber, as she reported in 2001, was about $1,155 per metric ton. This is less than 60 cents per pound which, according to Ms. Vantreese, is below most estimated U.S. production costs.

According to the Hemp Industries Association website, over 30,000 acres of cannabis were planted in 1999 in Canada. What they fail to mention is that acreage planted since then has declined dramatically. According to a Canadian Agricultural trade paper, *The Western Producer*, only 3,250 acres were licensed for planting in 2001, less than 1/10th of what was planted in 1999. In an article published by the *Minneapolis Star Tribune* in October 1999, Bob L'Ecuyer, General Manager of

Kenex, described in the article as "Canada's biggest hemp operation," stated "Everyone thought this would be a godsend, but it hasn't worked out that way." Mr. L'Ecuyer, referring to the over 30,000 acres planted in Canada, added, "There has been a major overestimation of the market that's out there."

The U.S. Department of Agriculture (USDA) arrived at similar conclusions in 2000. The USDA concluded that the total quantity of "hemp" fiber, yarn, and fabric imported by the United States in 1999 could have been produced on less than 2,000 acres. In terms of textiles, the closest competitor to "hemp" is linen, which is derived from textile flax. "Hemp" fiber, yarn, and fabric imports for the period January – September 1999 represented just 0.5% of U.S. linen yarn, thread, and fabric imports. The USDA concluded that the absence of a thriving linen production sector in the United States suggests that "hemp" will be unable to sustain adequate profit margins for a large production sector to develop.

The USDA further estimated the North American demand for cannabis, or "hemp", seeds to be 1,300 tons at an average price of 39 cents per pound. They further estimated that it would take only 2,600 acres to satisfy this demand for seed. The USDA concluded that the cannabis seed market will likely remain a small market, like the markets for sesame and poppy seeds. Indeed, the Hemp Food Association declares on their website that "hempseed product sales are well under $2 million annually in North America at retail."

I hope that this letter addresses your concerns. If you have any questions regarding this matter, please do not hesitate to contact me.

Sincerely,

Asa Hutchinson
Administrator