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The Honorable George Miller
2205 RHOB
Washington, D.C. 20515

June 17, 2002

Dear Representative Miller:

We have learned that you may have recently received a letter from Drug Enforcement Administration (“DEA”) Administrator Asa Hutchinson, dated April 23, 2002, which responded to the letter sent by 22 members of the House of Representatives to the DEA, on March 6, 2002, regarding the status of hemp seed and oil products. Administrator Hutchinson’s April 23rd letter is replete with misrepresentations of the facts and the law as they apply to this industry. The Administrator attempts to demonstrate that hemp seeds and derivative food products are already controlled substances under federal law, and alleges that the trace miniscule amount of THC (tetrahydrocannabinol, the psychoactive ingredient in marijuana) naturally present in seeds from industrial hemp has the potential to cause positive drug tests and psychoactivity. These claims are intended to support the legitimacy of DEA’s recent issuance of their “Interpretive,” “Proposed” and “Interim” rules. If implemented, these rules would render illegal and threaten with prosecution under the Controlled Substances Act (CSA) the manufacture, distribution and consumption of hemp food products containing any amount of THC, no matter how minute and insignificant.

As the lead organization representing the interests of the hemp industry in North America, we appreciate the opportunity to correct the Administrator’s misrepresentations one by one.

First, industrial hemp varieties of cannabis, also referred to as “fiber” or “low-THC” hemp, should not be confused with marijuana varieties. The majority of Western countries differentiate cannabis based primarily on THC content, and permit the farming of low-THC varieties for fiber and seed (similarly, a St. Bernard and a Chihuahua are very different varieties of the same species). This distinction is formally affirmed in Article 28(2) of the United Nations’ Single Convention on Narcotic Drugs, 1961, to which the United States is a signatory party: “This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.” Unfortunately, as the DEA continues to confound non-psychoactive industrial hemp varieties of cannabis with psychoactive “marijuana” varieties, the U.S. is the only major industrialized nation to prohibit the growing and processing of industrial hemp. However, hemp seed and oil along with hemp fiber are legal for trade in the United States, and they have been imported every year since the Marihuana Tax Act was passed in 1937 for use in diverse industries. While the term “industrial hemp” is, as the Administrator states, not found in federal law, it does have a well-established meaning, referring to non-psychoactive cannabis varieties, and regulations in the EU and Canada conservatively mandate less than 0.2 and 0.3% of THC in the flowers, respectively. By contrast, marijuana varieties generally contain between 3 to 15% THC in their flowers. Because of their minimal THC content, flowers and leaves from industrial hemp have no value as a medicinal or recreational drug. However, at issue here is the less than 0.0005% trace THC present in the seeds and oil of industrial hemp grown under strict regulations in Canada and the EU. These seeds and oil continue to be sold legally in the U.S. for their exceptional nutritional profile (omega-3 rich essential fatty acids (EFAs) and well-balanced protein content).

Second, Administrator Hutchinson misrepresents the current legal status of hemp seeds. His letter suggests that because THC is a Schedule I substance and the CSA provides that any mixture, compound, etc. which contains any quantity of a Schedule I substance is itself a Schedule I substance, then hemp seeds and oil, and oil and seed products, even though they contain only trace insignificant amounts of THC, must therefore be Schedule I controlled substances as well. The Administrator fails to mention, anywhere in his letter, that sterilized hemp seed and oil are specifically and expressly exempted from control in the CSA, in the definition of “Marihuana”: 21 U.S.C. §802(16). He also omits the fact that, according to DEA’s regulations, the THC listed in Schedule I is *synthetic* THC—not the naturally occurring trace amounts of THC in hemp seed and oil. These regulations provide that THC refers to

“[s]ynthetic equivalents of the substances found in the plant, or in the resinous extractives....” 21 C.F.R. §1308.11(d)(27). Indeed, in its “Interpretive Rule,” DEA itself raises the obvious question: “Why would Congress exempt certain portions of the cannabis plant from the CSA definition of marijuana if such portions would nonetheless be subject to CSA control to the extent they contain THC?” 66 Fed. Reg. 51530, 51531 (Oct. 9, 2001). The answer is obvious: hemp seed and oil are not subject to CSA control, notwithstanding the presence of trace insignificant amounts of naturally occurring THC-containing resin. That intent of Congress is documented by the congressional record and reflected in the statute, which Congress has declined to modify for over six decades.

Third, the letter describes the circumstances of the DEA’s issuance of their “Interpretive Rule,” “Proposed Rule” and “Interim Rule.” It suggests that, “[i]n accordance with the Administrative Procedure Act (APA), the proposed and interim rules were submitted for public comment....” This is not true. In fact, the “Interpretive Rule,” which purported instantly to criminalize the possession and sale of edible hemp seed and oil products, was issued without any opportunity to comment, in blatant violation of the APA and the CSA. North American hemp food companies immediately challenged the “Interpretive Rule” in a petition filed with the U.S. Court of Appeals for the Ninth Circuit in San Francisco, and on March 7, 2002, the Court issued an order staying the “Interpretive Rule” pending the Court’s final disposition of the merits of the case. The case has now been briefed, argued and submitted for decision. The stay remains in effect and the “Interpretive Rule” is currently null and void.

Fourth, the Administrator suggests that the insignificant trace amount of naturally-occurring THC in hemp oil pressed from seeds harvested from low-THC hemp has the potential to cause psychoactivity. This claim is based on a gross misrepresentation of the scientific literature and has no factual basis. Thorough evaluations of the toxicology of THC have shown that such a claim is analogous to asserting that drinking fruit juice and eating poppy seed bagels will produce some sort of “high” on account of their insignificant trace alcohol and opiate content, respectively. The Administrator asserts that a 1997 Swiss study has demonstrated that even oil pressed from the seeds of cannabis varieties containing less than 0.3% of THC, i.e. “industrial hemp”, can produce a “high.” This claim seriously misstates the method used by the Swiss researchers (Lehman, T et al., 1997, *J. Anal.Toxicol.* **21**: 373-375) and misrepresents the study’s findings and their relevance to the consumption of hemp seed products commercially available in the U.S. As clearly stated in the publication and confirmed through personal communication with one of its authors, the oil administered to volunteers was not, as claimed by Administrator Hutchinson, produced by a “bonafide” Swiss manufacturer from cannabis containing less than 0.3% THC. Rather, the researchers produced in their laboratory cannabis seed oil, and purchased cannabis seed oil samples, from the seeds of both “fibre type” and “drug type” cannabis (high-THC cannabis was legal to grow for seed and oil production in Switzerland in the mid-1990’s, but is no longer). THC levels in the 25 oil samples varied from 3–1,500 µg/g (parts per million or ppm). According to the author, the oil containing 1,500 ppm THC originated from seeds harvested from high-THC cannabis in which an excessive quantity of residual high-THC resin was pressed along with the seed in producing the oil. Such oil was never imported into the U.S. market, even in the mid-1990’s. Only the 1,500 ppm THC hemp oil was administered to six volunteers at doses of one and two tablespoons respectively, resulting in an oral THC dose of 16 and 33 milligrams. It is well established that even the lower of these doses can cause psychoactive effects in humans. However, these findings are irrelevant to hemp oils from low-THC varieties commercially available in the U.S., which typically contain *less than 5 ppm* of THC, compared to the 1,500 ppm administered in the Swiss study. At these minute concentrations, even daily consumption of unrealistically high amounts of hemp oil results in a THC dose of well less than one-tenth of the well-established oral threshold dose (5 mg) at which no psychoactivity is produced in humans. Thus, the Administrator’s claim of peer-reviewed research demonstrating that oil from industrial hemp seeds can cause a “high” is based on an obvious misrepresentation of the scientific literature. It is also irrelevant to the hemp seed products currently available in the U.S. market.

Fifth, the Administrator raises the issue that eating hemp oil and seed products could interfere with workplace drug testing programs. Administrator Hutchinson refers to “...reports in peer reviewed scientific journals demonstrating THC-positive urine screens resulting from ‘hemp’ food consumption.” The Administrator fails to state that these studies are not relevant to the commercial products now found in the U.S. The mentioned studies, which were conducted in 1995-97, administered hemp oils containing often more than 150 ppm of THC, compared to the less than 5 ppm present in commercial hemp oil today. These studies used oil produced from improperly cleaned seeds harvested in China and Europe in the mid-

1990's and showed that eating one or several tablespoons of these oils resulted, in some cases, in positive urine tests for marijuana. The dramatic reduction in the THC levels in U.S. hemp food products observed since the mid-1990's was due to the replacement of poorly cleaned Chinese and European hemp seed by properly processed Canadian and European seeds harvested exclusively from low-THC cannabis. Thus, the findings of the studies referenced by the Administrator are no longer relevant to today's commercial hemp seed foods. The Administrator fails to mention that a more recent, comprehensive study (Leson, G. et al., 2001, *J. Anal. Toxicol.* **25**:691-698) in fact demonstrated that, at the current much lower trace THC concentrations and the correspondingly miniscule ingested THC doses, even extensive and extended daily intake does not cause confirmed positive urine tests according to federal testing protocols. Based on this and other studies, the North American hemp industry has adopted voluntary standards for trace THC in seeds and oil under the TestPledge program, which ensures that hemp food suppliers purchase seeds only from sources which follow proper farming and seed cleaning procedures and stay within the specified trace THC limits. A description of the program can be viewed online at <http://www.testpledge.com>. The Administrator furthermore supports his claim that oil from "industrial hemp seeds" may produce positive urine tests by referring to recent work performed by Dr. Huestis at the National Institute on Drug Abuse (NIDA). Undoubtedly, Dr. Huestis has been able to produce positive urine tests by administering hemp oil with high THC levels not representative of hemp oil sold in the U.S. market. However, as noted above, the occurrence of positive drug tests is a function of the THC dose ingested via hemp foods. Since the Administrator fails to provide information on both the THC concentration present in the oil used by Dr. Huestis and the amount of oil administered, his statement is without scientific value and practical relevance, and is deliberately misleading.

Sixth, the Administrator suggests that, in exempting from the new rule hemp products containing insignificant trace THC but which do not enter the human body, DEA has "tried to...strike a balance between products which cause THC to enter the body and those that do not", and that DEA has thereby "preserved the vast majority of the marketplace for products that are derived from cannabis." This distinction fails to support DEA's position, and only confirms that DEA's position is legally and practically indefensible. Either all parts of the plant in which THC naturally occurs are automatically controlled (regardless of how trace and insignificant the amount), or they are not. The Administrator's claim that in instantly criminalizing the sale and possession of edible hemp seed and oil products with trace insignificant THC content while preserving the legality of other hemp seed and oil products, the DEA has "preserved the vast majority of the marketplace", --even if it were true-- is besides the point. If there is no law that confers on the federal government the power to criminalize a legitimate business, such government action does not magically become more lawful depending on the size or scope of that business. The Administrator's claim that the DEA has "preserved 80% of the market for cannabis products", all of which DEA claims, at the same time, are illegal, only underscores the arbitrariness of DEA's action.

Seventh, the Administrator continues to deny the documented fact that prior to DEA's unlawful "Interpretive Rule," the Department of Justice (DOJ) had confirmed that DEA has no legal authority to ban the importation, possession or sale of hemp seed and oil products based on trace infinitesimal natural THC content. In his letter to the DEA Administrator on March 23, 2000, the chief of the Narcotic and Dangerous Drug Section of the Criminal Division of DOJ stated clearly that "we [DOJ] are not able to regulate or prohibit the importation of 'hemp' products based on any residual or trace content of naturally occurring THC.... [W]e presently lack the authority to prohibit the importation of 'hemp' products...."

Eighth, contrary to the Administrator's suggestion, there is absolutely no distinction to be made between the treatment of poppy seeds and hemp seeds (and oil derived from the seeds) under the CSA. As the Administrator explains, opium poppy and opiates are Schedule II controlled substances and the CSA defines "opium poppy" to include all parts of the poppy plant except the seeds. Thus, the Administrator explains, "poppy seeds are excluded from the definition of opium poppy." But it is equally true that hemp seeds are expressly and specifically excluded from the statutory definition of "marijuana." The Administrator further acknowledges that, "[w]hile it is true that poppy seeds may contain small amounts of codeine, morphine and thebaine, which are Schedule II controlled substances, . . . poppy seeds are not considered controlled substances, even if they contain opiates." By "contrast," the Administrator suggests, THC is a Schedule I controlled substance as is any material, compound, etc. which contains any quantity of a Schedule I substance, unless such materials, compound, mixture or preparation is expressly exempted elsewhere from control (which hemp seeds and oil in fact expressly are: 21 U.S.C. §802(16)).

Poppy seeds are expressly exempted from control from the relevant plant in their case, the “opium poppy”; therefore, the fact that they contain trace amounts of separately controlled substances, opiates, does not result in control of poppy seeds. Likewise, hemp seeds and oil are expressly exempted from control under the CSA because they are expressly excluded from the definition of the relevant plant in their case, “marijuana”; therefore, the presence of trace miniscule amounts of THC, a separately controlled substance, does not render them subject to the provisions of the CSA. The Administrator’s “distinction” between poppy seed and hemp seed simply does not exist.

Ninth, Administrator Hutchinson goes on to claim that hemp seeds and poppy seeds also should not be compared relative to their impact on the outcome of drug tests. He alleges that drug tests can determine whether a positive test for opiates was caused by the consumption of poppy seeds or by pharmaceutical products and recreational drugs, whereas the same is not possible for hemp foods. This statement is, again, misleading. In fact, for more than a decade, the outcome of workplace drug tests for opiate drugs has been confounded by the potential consumption of poppy seeds. To eliminate positive drug screening results caused by poppy seed consumption, the federal government ultimately raised in 1998 the cutoff concentration in urine for opiates, above which a sample is considered positive for opiates. It is true that drug test labs now are able to confirm whether a positive screening result for opiates is caused by poppy seeds rather than pharmaceutical products or heroin; however, it was not practically feasible to differentiate between poppy seed consumption and smoked or ingested opium except through raising the cutoffs in the urine. This situation is a complete analogy to cannabis: it is possible to differentiate between the dirty hemp oil of the mid-1990’s and the use of the FDA-approved synthetic THC pharmaceutical, Marinol® (used to improve appetite and alleviate nausea associated with chemotherapy and AIDS); but it was not practically feasible to differentiate between the mid-1990’s dirty hemp oil and smoked marijuana. However, in contrast to the poppy seed situation, regulatory and industry efforts in relevant hemp producing countries have addressed the false-positive problem at the source through plant breeding and thorough seed cleaning. This has resulted in much lower trace residual THC, that no longer interferes with drug testing programs at *current* federal cutoffs.

Tenth, the Administrator insists on misstating the issue in his discussion of whether there is some “safe” limit for “putting” THC in edible products. No one is “putting” THC in “candy bars,” just as no one is “putting” morphine in bagels. The suggestion that the presence of infinitesimal trace amounts of THC naturally occurring in hemp seed is comparable to allowing candy bar makers to deliberately put some small amount of heroin or LSD in candy bars is outrageous. Heroin and LSD are synthesized drugs that are intentionally manufactured for recreational drug purposes, and obviously no amount of such substances can be declared legal to be manufactured for the addition to food. The naturally occurring trace opiates in poppy seeds, the naturally occurring trace alcohol in fruit juices, or the naturally occurring trace THC in hemp seed and oil, are an entirely different matter. Without any manufacture, concentration or synthesis of any kind, the amount present in these edible products inherently remains miniscule and harmless. There is no question here of allowing “illegal drugs in food products” by permitting the sale of poppy seeds on rolls and bagels or hemp seed and oil in waffles, nutrition bars, etc. The “allowable amount” (i.e. “tolerance”) of trace opiates in poppy seeds or trace THC in hemp seed and oil could easily be established well below active levels, as the FDA has done for alcohol and innumerable other substances in foods. In fact, THC, unlike pesticides and heavy metals allowed at non-zero tolerances in the U.S. food supply, is not characterized by a high acute toxicity and is not a known or probable carcinogen, and as noted above, synthetic THC in pill form is an FDA approved Schedule III medicine that is prescribed everyday.

Eleventh, the Administrator asserts that it would be a waste of “taxpayer money” to establish tolerances for trace natural THC in hemp seed and oil. Actually, it is a waste of taxpayer money for DEA to harass legitimate businesses and consumers selling and eating a nutritious alternative to fish and flax, the traditional sources for the Essential Fatty Acids (EFAs) omega-3 and omega-6. The Administrator does not address the issue of the cost of criminal investigation, prosecution and sentencing of those who continue manufacturing and consuming hemp seed foods, and the colossal waste of money and time that would entail. Violation of the Controlled Substances Act is a serious offense, particularly with Schedule I substances. Examination of the sentencing guidelines for substances containing “any amount of THC” reveals the following: one, the “carrier,” i.e. the hemp oil containing an infinitesimal amount of trace THC, is counted in determining the amount of the drug in question; and two, once the “amount” is determined (i.e. the total weight of the hemp snack bars, bags of chips or bottles of oil in question), the

conversion formula is 167 times the equivalent amount of marijuana. Thus, a manufacturer with a pallet of 100 cases of hemp seed corn chips (twenty 8 oz. bags per case) in their warehouse, would have 1,000 lbs. of “THC” according to the DEA, which equals 167,000 lbs. of “marijuana” (or about 76,000 kilos) for sentencing purposes. It is the DEA’s illegal attempt to twist and contort the CSA to magically render a non-drug food product into a Schedule I substance which is an enormous waste of taxpayer money and critical resources at a time when law enforcement agencies like DEA are already stretched thin.

Twelfth, the Administrator points out that hemp seeds and oil have not been formally affirmed as “generally recognized as safe” (GRAS) by the FDA. Particularly in the “natural foods” sector, this is not unusual and does not imply that a food is not safe for human consumption. For instance, flax oil was sold in the U.S. market for years before obtaining FDA affirmed GRAS status in 1998. Be that as it may, the hemp industry plans to petition the FDA to affirm GRAS status for hemp seed and present scientific evidence on the safety and nutritional value of these products, once the current situation with the DEA is resolved.

Finally, the Administrator concludes his letter by belittling the size and scope of the hemp industry. Edible hemp seed and oil products are beneficial for consumers and there is an established and growing demand for them. It is not DEA’s role to determine whether or not a legitimate, lawful industry is viable or profitable and to use the allegedly small demand for a product as one of the considerations in outlawing it. Indeed, that the Administrator has found it necessary to resort to the mistaken reasoning, “we may as well make this illegal, few people really want it and it looks like no one is making money on it,” only underscores the indefensible and arbitrary nature of DEA’s efforts to outlaw an industry which Congress decided, over six decades ago, should be preserved and encouraged.

We hope this addresses the Administrator’s points in his letter. If you have any questions concerning the above, please contact us. Thank you very much for your time and interest in this important matter.

Sincerely,

Eric Steenstra
President
Vote Hemp, Inc.