

December 10, 2001

By Hand

Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
600 Army Navy Drive
Arlington, VA 22202

**Re: Comments on Proposed Rule, Clarification of Listing of
“Tetrahydrocannabinols” in Schedule I**

Attention: DEA Federal Register Representative/CCD

Dear Deputy Assistant Administrator:

These comments are submitted on behalf of Hemp Industries Association; Nutiva, Inc.; Tierra Madre, LLC; Hemp Oil Canada, Inc.; North Farm Cooperative; Kenex Ltd.; Nature’s Path Foods USA, Inc.; and Hempola, Inc., on the Proposed Rule published by the Drug Enforcement Administration (“DEA”) on “Clarification of Listing of ‘Tetrahydrocannabinols’ in Schedule I”, 66 Fed. Reg. 51535 (Oct. 9, 2001)(the “Proposed Rule”).

The individual companies submitting these comments (“Edible Hemp Products Companies”) manufacture, distribute and/or sell, in the United States, processed hemp seed or oil intended for human consumption, or food and beverage products containing processed

hemp seed or oil, which seed, oil or products contain non-psychoactive miniscule trace amounts of residual resin containing naturally occurring tetrahydrocannabinols (“THC”). The business of the individual companies is described in more detail below. Hemp Industries Association is a trade association representing more than 250 hemp oil, hemp seed and hemp fiber, hemp food, clothing, beverage and body care companies and retailers of such products.

On October 9, 2001, without opportunity for notice and comment, DEA published an “Interpretive Rule” purporting to “interpret” the Controlled Substances Act, 21 U.S.C. §§802 et seq., and DEA’s own regulations, to mean that “any product that contains any amount of THC is a schedule I controlled substance. . . .” 66 Fed. Reg. 51530 at 51533 (emphasis added). The “Interpretive Rule,” made effective immediately upon publication, had the effect of instantly transforming the long-standing business activities of the Edible Hemp Products Companies into a criminal offense. Pursuant to 21 U.S. §877, these companies have filed a Petition for Review of the Interpretive Rule with the U.S. Court of Appeals for the Ninth Circuit. Hemp Industries Ass’n v. DEA, No. 01-71662 (9th Cir., filed Nov. 15, 2001). The petitioners in that action also filed an urgent motion for stay of the Interpretive Rule pending review. The motion is pending before the Court and the Court has issued a briefing schedule for the Petition for Review.

The Proposed Rule would amend the language of DEA’s regulations, 21 C.F.R. §1308.11, to have exactly the same effect as the “Interpretive Rule.” As explained in detail below, the Proposed Rule should not be adopted because:

1. The plain language of both Schedule I of the CSA and DEA’s current regulations excludes hemp oil, cake and sterilized seed notwithstanding that such items include miniscule trace amounts of naturally-occurring THC. The legislative history of both the statute and the regulations is irrelevant; but even if DEA could lawfully take that history into account, that history does not in any way support DEA’s “interpretation” that Schedule I of the CSA or DEA’s current regulation covers hemp oil, cake or sterilized seed containing trace amounts of naturally-occurring THC.

2. Therefore, DEA is actually proposing to add these substances to Schedule I of the CSA. DEA has authority to do so only after conducting a formal rulemaking proceeding on the record after opportunity for a hearing. The rulemaking contemplated by the Proposed Rule does not comply with this requirement.

3. Further, in order to add any substance to Schedule I of the CSA, the DEA must find that the substance has a “high potential for abuse.” 21 U.S.C. §812(b)(1). DEA cannot possibly make such a finding in the case of hemp seed and oil, and oil and seed products intended for human consumption, notwithstanding the presence of miniscule traces of naturally-occurring THC, because the most reliable scientific research indicates that the consumption of edible hemp seed and oil, and of edible products containing such hemp seed or oil, even in amounts vastly exceeding normal use, cannot possibly have any psychoactive effect.

4. No policy rationale for the Proposed Rule can be found in the potential of edible hemp seed and oil, and seed and oil products, for interference with drug testing. The most recent and reliable scientific research indicates that consumption of food products containing hemp seed or oil with THC levels at or below the levels found in the seed and oil used in the subject products, does not result in “confirmed positives” in drug tests administered to individuals using or consuming such products extensively on a daily basis.

5. The Proposed Rule would have a significant impact on small business, trade and consumers. The survival of several of the companies has already been imminently threatened by issuance of the “Interpretive Rule.” The Proposed Rule would also harm environmentalists, farmers and others who have spent years to research, develop and commercialize industrial hemp food and beverage products and create markets for those products.

6. The Interpretive and Proposed Rules will have a significant impact on international trade and violates the international trade agreements NAFTA (North American Free Trade Agreement) and WTO (World Trade Organization). DEA did not provide any notice and opportunity to U.S. trading partners or foreign companies to provide input into the

Rules before implementation. DEA did not conduct and has not provided a risk assessment or any other science-based rationale for issuance of the Rules. DEA did not seek to minimize impact on international trade and has not similarly treated poppy seeds and their trace opiates.

BACKGROUND

A. Hemp Seed and Oil for Human Consumption

Industrial hemp is a commonly used term for a group of varieties of the species *Cannabis sativa* L. that are cultivated for industrial rather than drug purposes. It can be grown as a fiber and/or seed crop. For seed, hemp is harvested when the seed is mature and ready for combining. U.S. Dept. of Agriculture, “Industrial Hemp in the United States: Status and Market Potential” 7, 10 (Jan. 2000)(“USDA Study”). The statutory hemp exclusion established in 1937 enabled U.S. individuals and businesses to legally purchase, use, and trade in sterilized hempseeds, hempseed oil, hempseed cake, hemp fiber and products made therefrom. Hemp food, oil and fiber products are available throughout the U.S., Canada, the European Union and Asia, in accordance with international trade agreements including the NAFTA and the WTO. Manufacturers of these products have invested years of time and millions of dollars in R&D and marketing and have created numerous jobs in reliance on the well-settled hemp exclusion to the Controlled Substances Act.

The seed is botanically an “achene” or small nut. Seeds are separated and cleaned; oil is predominantly extracted through a mechanical “cold pressing” process. See Thompson, Berger & Allen, “Economic Impact of Industrial Hemp in Kentucky” Fig. 1 at 5 (Univ. of Kentucky Center for Business & Economic Research, July 1998)(“Kentucky Study”). Most of the seed’s value is derived from either dehulling the whole seed and/or crushing it for oil.

According to the USDA Study, “Hemp seeds can be used as a food ingredient or crushed for oil and meal. The seed contains 20 percent high-quality digestible protein, which can be consumed by humans. . . The oil can be used both for human consumption and industrial applications.” USDA Study at 15. The oil content of hemp seeds varies from 30% to

40%. Hemp seed oil typically contains 75-80% of the poly-unsaturated essential fatty acids (EFA's) that are needed by, but not naturally produced by, the human body. I. Bocsa and M. Karus, The Cultivation of Hemp: Botany, Varieties, Cultivation and Harvesting 38 (1998). According to the Kentucky Study, the basic reasons for use of hemp oil in foods are that "hemp oil has a better profile of key nutrients, such as essential fatty acids and gamma-linolenic acid, than other oils, . . . and a similar profile of other nutrients, such as sterols and tocopherols." The seed meat also shows a high protein efficiency ratio. Kentucky Study at 7-8. Linoleic acid and alpha-linolenic acid are present in hemp oil in the ratio of 3:1, which is the optimal ratio for health benefits. Dr. Udo Erasmus, an internationally recognized nutritional authority on the subject of oils and fats, states: "Hemp seed oil may be nature's most perfectly balanced oil. It contains an ideal 3:1 ratio of omega-6s [linoleic acid] to omega-3s [alpha-linolenic acid] for long-term use, and provides the omega-6 derivative gamma-linolenic acid (GLA)." Erasmus, Fats That Heal, Fats That Kill 127 (1999).

This superior nutritional profile makes hemp seed and oil ideal for a wide range of food applications. Hulled hemp seeds resemble sesame seeds in appearance and are comparable to sunflower seeds in taste. They may be incorporated in baking or simply added to foods such as soups or salads. Consumption of hulled hemp seed blended in shakes or drink mixes offers an alternative to meet both daily protein and EFA needs. Hemp nuts may be ground and turned into nut butter for spreads and sandwiches. In the U.S., research is being conducted to use hulled or whole hemp seeds in the production of "hemp milk" as an alternative to soy or rice based non-dairy milks, a category that is now the largest selling in the natural foods business. The USDA study identifies food products containing hemp ingredients to include roasted hulled seed, nutrition bars, tortilla chips, pretzels and beer. *Id.* Firms have also attempted to develop products including cheese, margarine and candy bars. Kentucky Study at 7. Because it is tasty and less sensitive to heat than other high omega-3 oils, particularly flax oil, hemp oil can be used for cold dishes like sauces, flavorings, and dressings, and for low-heat cooking and sautéing. Leson and Pless, Hemp Foods and Oils for Health (1999).

B. The Edible Hemp Seed and Oil Products Industry

The companies currently selling hemp seed and oil food, beverage and nutritional products in the U.S. generally either import hemp seed and oil from Canada or Europe for use in manufacturing products in the U.S., or import already finished products from Canada or Europe. The Edible Hemp Products Companies submitting these comments are part of an industry including at least 20 firms located in the U.S. and Canada manufacturing and distributing edible hemp seed and oil or oil and seed products, most of them distributing or exporting to the United States. These 20 firms include:

Nature's Path Foods, U.S.A, Inc., a subsidiary of Nature's Path Foods of British Columbia, Canada, located in Blaine Washington, which produces and sells in the U.S. a hulled hemp seed cereal that is a top-selling cereal in the American natural food marketplace, and produces in Canada, and sells in the U.S., toaster waffles containing hulled hemp seed.

Nutiva, Sebastapol, California, which manufactures and sells throughout the U.S. hemp food products including bars, chips and cans of shelled hempseeds, all using shelled hemp seeds.

Tierra Madre, LLC, Lexington, Kentucky, which has developed a non-dairy hemp beverage, manufactured from processed hemp seed, which beverage the company is about to distribute throughout the U.S.

Hemp Oil Canada, Inc., a company based in Ste. Agathe, Canada, with a subsidiary in the United States, which markets, sells and distributes hemp oil and seed products including hemp seed oil, gencaps, hulled hemp seed, toasted hemp seed, hemp flour and hemp coffee in the United States.

North Farm Cooperative, Madison, Wisconsin, which distributes food products made from hemp seed including breads, bars, waffles and granola.

Hempola, Inc., Barrie, Ontario, Canada, which manufactures in Canada and sells throughout North America hemp seed oil, supplements, salad dressings and hemp flour, pancake mix and pasta.

Kenex, Ltd., a company based in Chatham, Ontario, Canada, with a subsidiary in the United States, which grows and processes industrial hemp in Canada and markets, sells and distributes hemp seed oil and hulled hemp seed, and hemp seed and oil products in the United States.

The Ohio Hempery, Inc., Guysville, Ohio, which produces and sells in the U.S. edible hemp seeds and oil.

Chi Hemp Industries, Inc. (CHII), Victoria, British Columbia, Canada, which produces and sells a hemp snack bar.

Hempzel Pretzels & Lancaster Hemp Co., Lancaster, Pennsylvania, which manufactures and distributes hand-rolled hemp pretzels in the U.S.

Humboldt Hemp Foods, Whitethorne, California, which manufactures and distributes coffee/hemp blends, roasted hempseeds and cake mixes made with hemp.

The Galaxy Global Eatery, a restaurant and store located in New York, NY, featuring hempseed oil, coffee/hemp blends, hulled hempseeds and fine hemp food cuisine.

Earthy Foods, Inc., San Pablo, California, which manufactures and distributes a hemp seed nutrition bar.

Govinda's, San Diego, California, which sells a hemp snack bar.

The Hemp Club, Inc., Toronto, Ontario, Canada, which distributes hulled hempseed and hemp flour.

Ruth's Hemp Foods, Toronto, Canada, which manufactures and sells hemp chips, pasta, and salad dressing.

The Cool Hemp Company, Inc., Killaloe, Ontario, Canada, which manufactures and sells a non-dairy frozen dessert made from hemp seed in several flavors.

Echo Oils, Inc., Christina Lake, British Columbia, Canada, which produces and sells hemp seed and hemp oil.

BioHemp Technologies, Ltd., Regina, Saskatchewan, Canada, which distributes hemp seed animal feed.

Natural Hemphasis (Fast Fuel Up), Toronto, Ontario, Canada, which manufactures and distributes hemp nutrition snack bars.

Although all of these companies are listed to provide more information about the scope and size of the hemp foods industry (estimated to total more than \$5 million in the U.S.), these comments are being submitted only on behalf of the Edible Hemp Products Companies listed at the beginning of the comments.

C. Trace Natural THC Content of Hemp Seed and Oil and Oil and Seed Products

Non-psychoactive industrial hemp plants grown in Canada and Europe are bred to contain less than three-tenths of one percent (< 0.3%) by weight of THC in the upper portion of the flowering plant. (USDA Study at 7), in full compliance with Article 28(2) of the United Nations' Single Convention on Narcotic Drugs, 1961, to which the U.S. is a signatory party. ("This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fiber and seed) or horticultural purposes"). The meat of the hemp seed (or nut) itself contains only miniscule traces of THC, usually much less than 0.5 parts per million (ppm, equivalent to microgram per gram - $\mu\text{g/g}$) of THC; however, the "[p]resence of THC in hemp seed products is predominantly caused by external contact of the seed hull with cannabinoid-containing resins in bracts and leaves during maturation, harvesting, and processing." Leson, Pless, Grotenhermen, Kalant and ElSohly, "Evaluating the Impact of Hemp Food Consumption on Workplace Drug Tests," 25 Journal of Analytical Toxicology

691, 692 (Nov./Dec. 2001). Consequently, hemp oil may contain trace amounts of THC from the trace resin residue on the outer shells. See Ross et al., “GC/MS Analysis of the Total delta-9-THC Content of Both Drug and Fiber Type Cannabis Seeds” (2000). (See also testimony of Dr. Herbert J. Wollner, consulting chemist for the Treasury Department, before U.S. House Ways & Means Committee during hearings for the 1937 Marihuana Tax Act, at Section I (B) infra). “Since 1998, more thorough seed drying and cleaning appears to have considerably reduced THC levels in seeds and oil available in the U.S.” Leson, Pless, Grotenhermen, Kalant and ElSohly, supra, at 692. Currently, THC levels in hulled seeds produced in Canada are typically less than 2 ppm and in hemp seed oil, 5 ppm. Id.

Recently the industry has taken steps to help assure consumers that hemp oil and shelled hempseed intended for human consumption will not exceed these levels. Under the “TestPledge” program, described in a website reproduced and attached hereto as Exhibit 1, producers and processors of hemp oil and shelled hemp seed must commission tests for THC content on every lot of shelled hemp seed and oil, performed by a laboratory properly accredited by Health Canada. These tests must demonstrate that hemp oil contain no more than 5 ppm of THC and that shelled hemp seed contain no more than 1.5 ppm of THC. All companies purchasing hemp seed and oil for distribution at wholesale or retail, and all companies purchasing these items for use in manufactured edible products, must obtain and retain copies of the tests for each lot of shelled hemp seed and oil that the companies have purchased. The objective of this self-regulation is to protect consumers of hemp foods from the risk of a positive workplace drug test and any other undesirable health effects.

DISCUSSION

I. DEA’S Proposed Rule Is Not a Mere “Clarification” of Existing Law But the Scheduling of a New Substance on Schedule I

DEA claims that its Proposed Rule “will clarify that, under the CSA and DEA regulations, the listing of ‘Tetrahydrocannabinols’ in schedule I refers to both natural and synthetic THC.” Proposed Rule, 66 Fed. Reg. at 51535. DEA explains that, as set forth in the “Interpretive Rule” issued simultaneously, “DEA interprets the current CSA and DEA

regulations such that any product that contains any amount of tetrahydrocannabinols is a Schedule I controlled substance, even if such product is a ‘hemp’ product (i.e. a product made from portions of the cannabis plant that are excluded from the CSA definition of marijuana).” *Id.* (emphasis added). It is clear, however, that the naturally occurring miniscule trace amount of THC in hemp seed and oil is not currently a Schedule I controlled substance. Therefore, DEA’s Proposed Rule is not a mere “clarification” of existing law, but is legally adding this substance to Schedule I. Indeed, the sole intent and effect of this “interpretation” is to schedule statutorily exempted hemp seed and oil as Schedule I controlled substances.

A. The Plain Language of the CSA and DEA’s Regulations Exclude Naturally Occurring Trace Amounts of THC in Hemp Seed and Oil

The CSA controls two materials relevant here: the Cannabis sativa plant itself, and synthetic THC. CSA Schedule I (c)(10), 21 U.S.C. §812(c) covers “Marihuana,” which is defined to include “all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or resin.” 21 U.S.C. §802(16). The Cannabis sativa plant itself is covered in Schedule I regardless of its THC content. New Hampshire Hemp Council, Inc. v. Marshall, 203 F.3d 1 (1st Cir. 2000). Thus, industrial hemp plants themselves are controlled under Schedule I.

The CSA definition of “Marihuana,” however, explicitly provides that:

Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from seeds of such plant, any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil or cake, or the sterilized seed of such plant which is incapable of germination.”

21 U.S.C. §802(16) (emphasis added).

The express language of the CSA thus provides that hemp oil, cake and sterilized seed are not controlled as “Marihuana” under Schedule I of the CSA.

CSA Schedule I(c)(17), covers “any material, compound, mixture or preparation, which contains any quantity of” THC (emphasis added). DEA’s regulations similarly provide that “THC” refers to “[s]ynthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp., and/or synthetic substances, derivatives, and their isomers. . .” 21 C.F.R. §1308.11(d)(27)(emphasis added). Thus, it is clear that “THC”, as used in CSA Schedule I, does not refer to the organic, naturally-occurring THC found in hemp oil, cake and sterilized seed, but only to synthetic THC. There is no present or potential class of cannabinoid abuse that the current regulatory language in the CSA does not already cover: hypothetical pure natural THC extracted and refined from the flowers and resin is already covered under the CSA as a derivative of the resin.

If a statute is clear and unambiguous, Congress’s intent must be upheld and the contrary interpretation of an agency is not entitled to deference. Immigration & Naturalization Service v. Cardoza-Fonseca, 480 U.S. 421 (1987). “[I]f the statute is clear and unambiguous, ‘that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.’” Mobil Oil Expl & Prod. Southeast, Inc. v. United Dist. Cos., 498 U.S. 211, 223 (1991), quoting Sullivan v. Stroop, 496 U.S. 478, 482 (1990).

Similarly, an agency is entitled to deference with respect to interpretation of its own regulations, but such deference is due only where regulations are “ambiguous,” Christensen v. Harris County, 529 U.S. 576, 588 (2000). An agency’s interpretation is not given controlling weight where it is “plainly erroneous or inconsistent with the regulation.” Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 521 (1994). No deference is due an interpretation of a regulation that is “plainly erroneous or inconsistent with the plain terms of the disputed regulation.” Federal Election Commission v. National Rifle Ass’n, 254 F.3d 173, 181 (D.C. Cir. 2001), quoting Everett v. United States, 158 F.3d 1364, 1367 (D.C. Cir. 1998).

In this case, the language of the CSA is clear. The definition of marijuana explicitly and plainly excludes hemp oil and seed. CSA Schedule I(c)(17) refers to synthetic THC only, on its face. And the DEA’s regulation refers only to “synthetic” equivalents of the substances

contained in the plant or the resin. In these circumstances, DEA cannot “interpret” or “clarify” either the CSA or DEA’s own regulations to mean otherwise than what their texts plainly state. For this reason alone, the naturally occurring trace amounts of THC present in hemp seed and oil are not currently controlled substances under Schedule I.

B. The Legislative History of the Definition of “Marijuana” Makes It Clear That Congress Intended to Exclude Sterilized Hemp Seed and Oil Notwithstanding Trace Amounts of THC (i.e. Drug-Containing Resin)

Even if the legislative history of the statutory definition of marijuana were relevant, that legislative history fails in any way to support DEA’s “interpretation” of the CSA. In its “Interpretive Rule,” DEA acknowledges that the “definition [of marijuana] that appears in the CSA today is identical to the definition that was contained in the Marihuana Tax Act of 1937.” 66 Fed. Reg. at 51530. “The 1970 Congress seems to have adopted the definition of marijuana from the 1937 Marihuana Tax Act without reported discussion.” Id. DEA further acknowledges that it makes little sense for “Congress [to] 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.” Id. at 51531. DEA’s answer is that “the 1970 Congress did not address the possibility that portions of the cannabis plant excluded from the definition of marijuana might contain THC.” In DEA’s view, “it is evident that the 1937 Congress exempted certain portions of the cannabis plant based on the assumption (now refuted) that such portions of the plant contain none of the psychoactive component now known as THC.” Id. To the contrary, the legislative history clearly demonstrates that the 1937 Congress was well aware that hemp seed, and the oil derived from it, contain trace amounts of the drug-containing resin (the active constituent of which, natural THC, was subsequently identified in the early 1960’s), but that Congress was convinced that such amounts are not sufficient to be harmful.

At hearings before the House Ways and Means Committee in April 1937, Clinton Hester, Assistant General Counsel for the Treasury Department, testified that, “As the seeds, unlike the mature stalk, contain the drug, the same complete exemption could not be applied in this instance.” Hearings on H.R. 6385, 7th Cong., 1st Sess. 8 (April 1937). Similarly, H.J.

Anslinger, Commissioner of Narcotics of the Bureau of Narcotics of the Treasury Dept., stated that the Bureau had “urged the States to revise their definition so as to include all parts of the plant, as it now seems that the seeds and portions other than the dried flowering tops contain positively dangerous substances.” *Id.* at 19. However, later, Dr. Herbert J. Wollner, consulting chemist for the Treasury Department, clarified for the Committee that:

The active principle in marihuana appears to be associated with an element which is located or found in the flowering tops and on the under side of the leaves of the plant. . . . The resin contains an ingredient which the chemical technologist refers to as cannabione or cannabino, alternatively...[S]eeds contain a small amount of that resin, apparently on their outer surface according to quite a number of investigators depending upon the age of that seed....

Id. at 52-54 (emphasis added).

At the same time, the Ways and Means Committee heard considerable testimony to the effect that the very small amounts of the "active principle", i.e., THC, potentially present in hemp seed and oil would not have any harmful effect or potential for abuse. Mr. Wollner goes on to testify that the “small amount of that resin” is indeed negligible and harmless and technically very difficult to extract and concentrate (and thus economically prohibitive):

Mr. Buck [Rep. Frank Buck (D-Cal)]: Does the oil from the seed contain any of this deleterious matter?

Mr. Wollner: That would in a large measure depend upon the condition of the seed and the condition of manufacture, but I would say in any event the oil would not contain a large amount of this resin....

Mr. Buck: Would it contain enough to have any harmful effect on anyone, if taken internally?

Mr. Wollner: I would say no; it would not contain such an amount.

Mr. Fuller [Rep. Claude Albert Fuller (D-Ark.)]: As I understand it, you say the oil does not contain much, if any, of the drug?

Mr. Wollner: It does contain some of the drug, but not much. It would appear, offhand, to be rather difficult to separate, but processes might possibly be developed for that purpose.

Mr. Fuller: It would not be useful for the purpose for which they are using marihuana.

Mr. Wollner: No.

Mr. Fuller: So, so far as the oil from the seed is concerned, it is harmless, as far as human use is concerned.

Mr. Wollner: That is right.

Id. at 54 (emphasis added). Similarly, during the testimony of Ralph Lozier, general counsel of the National Institute of Oilseed Products, before the Committee, the following exchange took place indicating congressional awareness of the insignificant harmless quantity of trace resin in the seed (also note Mr. Lozier makes Congress aware that hemp seed is so safe that it is consumed extensively as food in southeast Asia):

Mr. Lozier: ... No one will contend, or no respectable authority will assert, that this deleterious principle is found either in the seed or the oil..... .If the committee please, the hemp seed, or the seed of cannabis sativa, L., is used in all the Oriental nations and also in a part of Russia as food. It is grown in their fields and used as oatmeal. Millions of people every day are using hemp seed in the Orient as food. They have been doing that for many generations, especially in periods of famines.

Mr. Fuller: I do not think that the gentlemen who have presented the case on behalf of the committee, or the Government, have claimed that it was present in the oil.

Mr. Lozier: They have said it was in the seed.

Mr. Fuller: He said there was very little in the seed. He said there would be no injurious effect from the little there was in the seed.

Id. at 61 (emphasis added).

The Committee's report on the bill it reported out, H.R. 6906, makes clear that the Committee recognized that "marihuana is a dangerous drug found in the flowering tops, leaves and seeds of the hemp plant,..." H. Rep. 792, 75th Cong. 1st Sess. 1 (1937) (emphasis added), but that whatever amount was present in the seeds would not be harmful or have the potential for abuse:

The term "marihuana" is defined so as to bring within its scope all parts of the plant having the harmful drug ingredient, but so as to exclude the parts of the plant and the valuable industrial articles produced therefrom in which the drug is not present.

Id. at 3-4 (emphasis added).

Likewise, the Senate Finance Committee heard testimony making clear that hemp seed and oil contain trace amounts of resin (i.e. THC), but that these miniscule amounts would not

have any harmful effect or be capable of abuse. In July 1937 hearings before the Finance Committee, Mr. Hester of the Treasury Department testified that:

Mr. Hester: The flowering tops, leaves and seeds of the hemp plant contain a dangerous drug known as marihuana....

Senator [Prentiss Marsh] Brown [(D-Mich.)]: Say you are in this situation. You have a plant that produces several articles that are valuable commercially.

Mr. Hester: That is right.

Senator Brown: At the same time, as a byproduct the leaves and the seeds can be used for marihuana?

Mr. Hester: That is right.

U.S. Senate Finance Committee, Hearings on H.R. 6906, 7th Cong., 1st Sess. 9 (1937)(emphasis added). Commissioner Anslinger made clear to the Finance Committee his understanding that, while hemp seed definitely contained resin (i.e. THC), it was likely that sterilization would render its effects harmless:

Senator Brown: Do I understand that the seed is ground up, too, and used to any extent?

Mr. Anslinger: Well, we have heard of them smoking the seed.

Senator Brown: Does it produce the same effect?

Mr. Anslinger: I am not qualified to say. We have not made any experiments to that, but we do know that the seed has been smoked. I think that the proposition of the seed people sterilizing the seed by heat and moisture will certainly do a lot to kill this traffic.

Id. at 13. At the same time, the Finance Committee heard testimony from Matt Rens, of Rens Hemp Company of Brandon, Wisconsin, explaining that:

No evidence has been obtained, either by scientific investigation or by practical observation to indicate that hemp seed, as handled in the trade, contains an appreciable proportion of the chemical substances which cause the narcotic effect.

. . . A recent and thorough-going inquiry indicates that there are no biological tests or other researches which show that narcotic-producing substances are present in the seeds in a sufficient proportion to be harmful, in fact, there is nothing that shows that true seeds cause any of the narcotic effects. . . .

The technical evidence given in the [House] hearings. . . shows that the seed does not contain an appreciable proportion of the narcotic substances. The [House] hearings also show that the seed was considered so harmless as to warrant omitting sterilized hemp seed from the definition of marihuana. . . . There is also no evidence, either practical or technical, to show that hemp seed has ever been used to produce the drug effect.

Id. at 24 (emphasis added). After hearing such testimony, the Finance Committee followed the House Ways and Means Committee in concluding that, while hemp seed does contain resin (i.e. THC), it should be excluded from the definition of marijuana because such seed does not contain enough resin/THC to be considered a “harmful drug:”

The flowering tops, leaves, and seeds of the hemp plant contain a dangerous drug known as marihuana. . . .The term “marihuana” is defined so as to bring within its scope all parts of the plant having the harmful drug ingredient, but so as to exclude the parts of the plant in which the drug is not present. The testimony before the committee showed definitely that neither the mature stalk of the hemp plant nor the fiber produced therefrom contains any drug, narcotic, or harmful property whatsoever and because of that fact the fiber and mature stalk have been exempted from the operation of the law.

S. Rep. 900, 75th Cong., 1st Sess. 1, 4 (1937) (emphasis added).

DEA cites an excerpt from this Senate Finance Committee Report to support the notion that Congress exempted “certain portions of the cannabis plant from the definition of marijuana based on the assumption (now refuted) that such portions of the plant contain none of the psychoactive component known as THC.” 66 Fed. Reg. at 51531. Yet the very language cited by DEA from that Report—the language set out above—states explicitly the Committee’s understanding that “neither the mature talk of the hemp plant nor the fiber produced therefrom” contain any “drug” property. No reference is made in that phrase to the seeds of the hemp plant. It is thus obvious that the Committee did understand that the seeds do contain the “drug” property; indeed, the Committee report states explicitly that the “seeds of the hemp plant contain a dangerous drug....” Yet the Committee, and ultimately Congress, excluded nonviable hemp seed and oil from the definition of marijuana. The only logical conclusion is that Congress was fully aware that hemp seed and oil do contain trace amounts of resin (THC), but that Congress excluded hemp seed and oil anyway because it was understood that these trace amounts were insufficient to be abused or to be economically extracted and concentrated for drug purposes.

Thus, contrary to DEA’s suggestion, the legislative history of the 1937 law shows that Congress was indeed aware that hemp seed and oil contain trace amounts of resin/THC, but

that Congress nevertheless excluded such seed and oil from the definition of “marijuana” because Congress also understood that these trace amounts would not be harmful or capable of abuse.

For precisely that reason, DEA’s reliance on United States v. Walton, 514 F.2d 201 (D.C. Cir. 1975), is utterly misplaced. In that case, a defendant who was convicted of distribution of marijuana indisputably intended for drug use argued that the CSA covered only one species of marijuana. The Court held that Congress “meant to outlaw all plants popularly known as marijuana to the extent those plants possessed THC.” 514 F.2d at 203-04 (emphasis added). It was in that context that the Court stated that “the definition of marijuana was intended to include those parts of marijuana which contain THC....” Id. at 203. The Court had no occasion to address, and did not address, the issue of whether the CSA covers naturally occurring trace THC present in the parts of the marijuana plant specifically excluded by the CSA definition of marijuana. Indeed, the Court cited the same Senate Finance Committee report language discussed above. Id. at 203 n.9. And as we have shown, that language can only be understood to mean that as to hemp seed and oil, Congress knowingly exempted those parts of the plant despite knowledge that such parts may contain trace amounts of THC.

Furthermore, the Department of Justice and DEA, in their “Memorandum of Points and Authorities in Opposition to Plaintiffs’ Motion for a Preliminary Injunction” submitted in the case of New Hampshire Hemp Council, Inc. v. Marshall, 203 F.3d 1 (1st Cir. 2000), acknowledge that the Walton court, in finding that the definition of marijuana was intended to include those parts of marijuana which contain THC, was not addressing the exclusion of hemp seed from the definition of marijuana, but only the exclusion of the mature stalk:

The Walton court also stated that ‘we find that the definition of marijuana was intended to include those parts of marijuana which contain THC and exclude those parts which do not.’ 514 F.2d at 203 (citing legislative history of 1937 Act). The Walton court was apparently referring to exclusion of “the mature stalks” from the definition of marijuana. See 802(16); 1937 Act, 55 Stat. 551.

Defendant’s Memorandum of Points and Authorities, supra at 15 n. 7 (emphasis added).

For these reasons, the legislative history of the definition of marijuana only confirms that the Congressional intent was expressed in the plain language of the 1937 Act itself (the same language as that which appears in the CSA): hemp seed and oil are excluded from that definition.

C. The Historical Control of THC Under Federal Law Indicates That Schedule I Does Not Cover Naturally Occurring Trace THC in Hemp Seed and Oil

In an effort to demonstrate that the naturally occurring trace THC in the excluded parts of marijuana, i.e., hemp seed and oil, are currently covered by Schedule I of the CSA, DEA has constructed a post-hoc rationalization based on the history of control of THC under federal law. In fact, that history only serves to demonstrate that naturally occurring trace THC in the excluded parts of the marijuana plant has never been, and is currently not, controlled as “THC” in Schedule I of the CSA or DEA’s regulations.

As DEA concedes, until 1971 natural THC was federally controlled only under the Marihuana Tax Act, and the definition of THC “included natural THC (to the extent such THC was contained in, or derived from, those portions of the cannabis plant included in the definition of marijuana).” Interpretive Rule, 66 Fed. Reg. at 51532. Since hemp seed and oil were portions of the plant excluded from the definition of marijuana, it is clear that naturally occurring THC in those portions was not controlled.

DEA points out that, “in the late 1960’s, when synthetic THC began showing up in the illicit market, federal officials concluded that federal control over the drug was necessary to prevent abuse.” Id. According to DEA, at that time, control of synthetic DEA could only be accomplished pursuant to the Drug Abuse Control Amendments of 1965, P.L. 89-74, 79 Stat. 226 (“DACA”). DEA explains that the 1968 Bureau of Narcotics and Dangerous Drugs regulation promulgated pursuant to DACA was limited to synthetic THC because DACA prohibited BNDD from promulgating a regulation that would list under DACA any substance included in the definition of marijuana under the Marihuana Tax Act of 1937. Id. Indeed, section 3 of DACA provided that the Secretary of HEW could designate “any drug which

contains any quantity of a substance which the Secretary...has found to have...a potential for abuse because of its depressant or stimulant effect...; except that the Secretary shall not designate...marihuana as defined in section 4761, of the Internal Revenue Code...” DACA, §3(a), adding 21 U.S.C. §321(v)(3).

This language clearly left BNDD free to designate any substance which was not included in the definition of marihuana in the Marihuana Tax Act. Since naturally occurring THC in sterilized hemp seed and oil were excluded from that definition, BNDD was entirely free to designate such THC under DACA. Nevertheless, BNDD’s regulation was identical to the current listing of THC in the DEA regulations, and was limited to synthetic THC. DEA contends that since “natural THC (derived from marijuana) fit within the definition of marijuana and was thereby controlled under the Marihuana Tax Act, the BNDD regulations listing THC had to exclude such natural THC.” 66 Fed. Reg. at 51532. But the natural THC occurring in the excluded parts of marijuana did not fit within the definition of marijuana; was not controlled by the Marihuana Tax Act; and therefore could legally have been controlled by BNDD in 1968. That BNDD chose not to do so only makes clear that the 1968 BNDD language—identical to that of DEA’s current regulation—was intended to, and did, exclude naturally occurring THC in hemp seed and oil and that DEA’s current regulation likewise excludes such naturally occurring THC.

DEA further contends that when Congress enacted the CSA in 1970, it listed “Tetrahydrocannabinols” in Schedule I “without having to distinguish between natural and synthetic.” Id. But at the same time, Congress separately listed “Marihuana” in Schedule I. If Congress truly intended the listing of THC to include all forms of THC, natural and synthetic, however and wherever occurring, such separate listing of marihuana would have been entirely superfluous. Indeed the manifest intent of Congress is explained by the question DEA itself raises: “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. at 51531. The answer is clear: such portions are not subject to CSA control to the extent they contain naturally-occurring THC.

Likewise, that BNDD carried forward the 1968 regulatory language into its 1971 regulations, 36 Fed. Reg. 4950 (March 13, 1971), adding new 21 C.F.R. §308.11(d)(17)—following enactment of the CSA—only confirms that the current regulatory language does not include any naturally-occurring THC. DEA makes much of the fact that the general term “Tetrahydrocannabinols” was added to the beginning of listing, above the references to “synthetic equivalents.” But if that listing was not intended to be limited to synthetic THC, there would be no reason for the listing of synthetic equivalents—rather, the one word would automatically include all forms of both naturally occurring and synthetic THC. It is obvious that the language under the word “Tetrahydrocannabinols” in DEA’s regulation is intended to define what is included in that listing. Indeed, it makes no more sense for DEA to list “Marihuana” separately in its regulation, with hemp seed and oil excluded only to be re-included as “THC,” then it would have for Congress to do the same thing.

It is clear that DEA’s reliance on the general term “Tetrahydrocannabinols” simply proves too much. Under DEA’s reasoning, DEA could find that the CSA currently includes poppy seeds (commonly consumed on bagels), which are explicitly exempted from the CSA in the statutory definitions of “opium poppy” and “poppy straw,” 21 U.S.C. §§802(19),(20), based on the fact that poppy seeds contain trace amounts of natural opiates, which have no abuse potential but which are in themselves clearly and unambiguously controlled under CSA, Schedule II(a)(1), 21 U.S.C. §812(c).

The history and structure of federal control of THC, then, makes clear that “THC” as listed in Schedule I of the statute, and in DEA’s regulation, excludes the naturally occurring trace THC in hemp seed and oil.

D. The Department of Justice Itself Interprets the CSA to Exclude Hemp Seed and Oil

That hemp oil, cake and sterilized seed are not currently controlled by the CSA Schedules has been confirmed by the Criminal Division of the U.S. Department of Justice, of which DEA, of course, is a part. In a letter to the DEA Administrator dated March 23, 2000, attached hereto as Exhibit 2, John Roth, Chief of the Narcotic and Dangerous Drug Section of

the Criminal Division of the U.S. Department of Justice, referring to the exclusion of hemp oil, cake and sterilized seed from the definition of “Marihuana” in 21 U.S.C. §802(16), stated:

Therefore, products derived from this portion of the cannabis plant commonly referred to as “hemp” are explicitly excluded from regulation under the Controlled Substances Act.

It has been suggested that “hemp” products containing THC are subject to regulation under 21 U.S.C. §812(17). However, 21 U.S.C. §812(17) refers only to synthetic THC, not the THC naturally occurring within marijuana. The pertinent regulation, 21 C.F.R. §1308.11(d)(27), defines THC as “synthetic equivalent of the substances contained in the plant. . . .”

Thus, it appears we are not able to regulate or prohibit the importation of “hemp” products based on any residual or trace content of naturally occurring THC. . . . [I]t is our legal opinion that we presently lack the authority to prohibit the importation of “hemp” products, absent regulatory language that interprets, or legislative action to modify, the definition of marihuana contained in 21 U.S.C. §802(16).

(emphasis added).

Significantly, an identical letter, dated March 22, 2000, attached hereto as Exhibit 3, was sent by Mr. Roth to then-U.S. Customs Commissioner Raymond W. Kelley. Thus, this statement of the current legal scope of the CSA was not merely a temporary “prior interpretation,” but was intended to have a “binding effect . . . on tribunals outside the agency. . . .” Splane v. West, 216 F.3d 1058, 1064 (Fed. Cir. 2000). Indeed, a subsequent letter from Commissioner Kelley to Office of National Drug Control Policy (ONDCP) Director Barry McCaffrey, dated March 31, 2000, (attached hereto as Exhibit 4), apparently informed ONDCP that the Department of Justice’s controlling interpretation contradicts ONDCP’s position, and advises ONDCP to work with the Department of Justice to effect ONDCP’s aims.

As long ago as 1991, DEA recognized that the CSA plainly does not currently control hemp seed or oil notwithstanding trace amounts of naturally occurring THC. In an April 18, 1991 affidavit (attached hereto as Exhibit 5), Charles M. Metcalf, a Senior Investigator of the DEA, stated:

...I am a Senior Investigator employed by the Drug Enforcement Administration (DEA) and am assigned to the DEA Office of Diversion Control, Registration Section...I am fully familiar with the facts stated herein...

7. The DEA, and my office in particular, is aware that sterile marijuana seed sold as birdfeed is likely to contain residue and particulate vegetable matter which will test positive for the presence of THC, the active ingredient in marijuana.

8. The DEA does not require sterile marijuana seed placed into commerce as birdfeed to be free from all such residue and particulate matter.

9. The DEA does not consider sterile marijuana seed sold as birdfeed to be a controlled substance, whether or not it contains residue or particulate matter which tests positive for the presence of THC.

10. As detailed in the Affidavit of Susan Miller, Forensic Chemist, DEA, when evaluating material which visually appears to be primarily marijuana seed, the DEA's determination of whether the material constitutes a controlled substance must be made by viability testing of the seeds, rather than separate THC analysis of the residue and particulate matter.

(emphasis added).

Likewise, Susan Miller, a DEA forensic chemist, stated in a corresponding April 11, 1991 affidavit (attached hereto as Exhibit 6):

"I am a Forensic Chemist employed by the Drug Enforcement Administration...

2. ...It is recognized by the DEA laboratory system that the residues associated with marijuana seeds can and most often do, produce positive THC results using the standard chemical tests for marijuana... For seed evidence, the chemist must prove by microscopic examination that the seeds have the physical characteristics of marijuana seeds, and the chemist must also prove that the seeds are viable.... Viability is the critical aspect of the analysis because the law specifically states that sterilized seeds incapable of germination are not included in the term "marijuana" and are therefore not controlled.

(emphasis added).

Thus, to identify whether or not the substance in question, hemp seed, is controlled, DEA ascertains only whether or not the seeds are viable, as viable marijuana seeds are defined as controlled, and sterilized hemp seeds are not, notwithstanding the presence of trace natural THC.

That the listing of THC itself in Schedule I(c)(17) is limited to synthetic THC has also been long acknowledged by DOJ. In United States v. Wuco, 535 F.2d 1200 (9th Cir. 1976), DOJ conceded that the listing of “Tetrahydrocannabinols” in Schedule I is limited to synthetic THC; the Court agreed that “organic THC. . . is not the synthetic THC defined as a Schedule I controlled substance.” Id. at 1202.

For these reasons, it is clear the CSA, and DEA’s current regulations, do not cover sterile hemp seed and oil, notwithstanding the presence of trace amounts of naturally occurring THC (viable seeds are covered by the CSA, not because of their THC content but because of their potential to produce marijuana plants). Therefore, what DEA is actually proposing to do in the Proposed Rule is to add to Schedule I a new substance—hemp oil and seed containing trace miniscule amounts of naturally occurring THC.

II. DEA Must Conduct a Formal Rulemaking In Order to Add a New Substance to Schedule I

To be sure, should DEA, against all common sense, be concerned that hemp seed and oil present an abuse potential that Congress did not foresee or overlooked, DEA has the authority to add new substances to the CSA Schedules. Indeed, DEA cites such authority as the basis for its Proposed Rule: “This proposed rule is being issued pursuant to 21 U.S.C. 811, 812 and 871(b). Sections 811 and 812 authorize the Attorney General to establish the schedules in accordance with the CSA and to publish amendments to the schedules. . . .” Proposed Rule, 66 Fed. Reg. at 51535.

The proceeding contemplated by the Proposed Rule, however, clearly does not comply with section 811 of the CSA and the Administrative Procedure Act. The Administrative Procedure Act, 5 U.S.C. §553 (“APA”), requires that agency regulations be promulgated through advance notice of rulemaking with an opportunity for public comment. Section 553(c) further provides that, “When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead. . . .” Under

sections 556 and 557, the agency must support its rule with substantial evidence based on a rulemaking record; there must be an oral hearing; parties must be afforded the opportunity for cross-examination; and parties must be permitted to present proposed findings and conclusions, and present exceptions to initial and recommended decisions.

Section 811 of the CSA delegates to the Attorney General the power, by rule, to add to a CSA schedule “any drug or other substance” if the Attorney General makes certain findings prescribed in the statute. 21 U.S.C. §811(a). Section 811(a) further provides that “Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by” the APA. *Id.* (emphasis added). Thus, Section 811(a) follows the exact language of the APA that requires formal rulemaking. See United States v. Florida East Coast Railway, 410 U.S. 224, 241 (1973).

Thus, to add hemp oil, cake and sterilized seed to any schedule of the CSA, the DEA must initiate a formal rulemaking process pursuant to section 556 and 557 of the APA, with an oral hearing, opportunity for cross-examination and the opportunity to present proposed findings and conclusions. DEA’s issuance of the Proposed Rule, with receipt and consideration of written comments only, clearly fails to comply with these requirements.

III. DEA Cannot Make the Findings Required to Place Hemp Seed and Oil on Schedule I

Pursuant 21 U.S.C. §812(b), substances cannot be listed on Schedule I “...unless the findings required for such schedule are made with respect to such drug or other substance.”

The findings required for Schedule I are as follows:

- (1) Schedule I. -
 - (A) The drug or other substance has a high potential for abuse.
 - (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
 - (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

21 U.S.C. §812(b)(1).

Based on the most reliable recent scientific research of which the Edible Hemp Products Companies are aware, there is no potential for abuse whatsoever, let alone a “high potential for abuse,” from ingestion of hemp seed or oil, or edible products made from hemp seed or oil. The most recent study that has come to the attention of the Companies is Grotenhermen, Leson & Pless, “Assessment of Exposure to and Human Health Risk from THC and Other Cannabinoids in Hemp Foods” (Oct. 11, 2001), a copy of which is attached hereto as Exhibit 7. This study concludes, first, that “[t]he lowest single oral THC dose, at which acute adverse neurological effects...have been observed, is 5 mg (for a body weight of 70 kg). This dose represents the LOAEL [Lowest Observed Adverse Effects Level] for acute effects caused by THC.” *Id.* at 6; *see id.* at 47-51. The study determined that “determination of an acceptable daily intake should be based on the LOAEL for reduced psychomotoric performance of 5 mg for a single dose, or 2 X 5 mg, taken orally over the course of a day. Considering that the observed psychomotoric effects are not severe and according to scientific practice, selection of a safety factor of 20 provides a sufficient margin of safety from acute adverse neurological effects. Based on the above, an acceptable daily intake (ADI) for orally ingested THC of 500 µg/day was assumed to provide protection from both acute and chronic adverse effects to humans.” *Id.* at 6.

The study then examines the potential intake of THC via hemp foods under various dietary scenarios. The study recognizes generally achieved THC levels in hemp seed derivatives are less than 2 ppm for whole seeds meal and flour; 1.5 ppm for hulled seeds and protein powder; and 5 ppm for hemp oil. *Id.* at 8. The “reasonable worst case” scenario assumes complete substitution of all meat and non-meat food items by hemp foods, wherever technically feasible; a high daily caloric intake at the 95th percentile of the U.S. population (3,182 kcal/day); and the use of the maximum technically conceivable hemp content in all food products. Under that highly conservative scenario, daily THC uptake via hemp food would not exceed 500 micrograms (µg), i.e., 0.5 mg per day. The study concludes that:

Consequently, the daily THC ingestion even by extensive users of hemp foods will remain consistently and, in general, significantly, below the proposed ADI [Acceptable

Daily Intake] for oral THC, and thus will not cause any acute or chronic adverse healthy impacts. Specifically, the highest conceivable intake of THC via hemp foods is far below the psychoactive threshold for THC. . . .

Generally achieved THC levels in hemp seed derivative—i.e., less than: 2 µg/g for whole seeds, meal and flour; 1.5 µg/g for hulled seeds and protein powder; 5 µg/g for hemp oil—should be considered by regulatory agencies as a conservative and enforceable choice of THC limits in hemp seed derivatives.

Id. at 7-8 (emphasis added).

For these reasons, it is clear that DEA cannot possibly make the finding of “high potential for abuse” that would be required to add to Schedule I hemp seed and oil, and edible seed and oil products, containing miniscule trace amounts of naturally occurring THC.

Indeed, apart from ensuring that sterilized seeds are indeed non-viable, DEA has no jurisdiction over hemp seed and oil, and hemp seed and oil products. Indeed, the CSA, 21 U.S.C. §811(g), prohibits the DEA from regulating substances already regulated under the Federal Food, Drug and Cosmetic Act. The Food and Drug Administration, FDA, under the FFDCFA, is the government agency that ensures food safety, and thus should be engaged in the regulation of hemp seed and oil foods, rather than DEA.

IV. Edible Hemp Seed and Oil Products Do Not Interfere With Drug Testing

Although DEA has not articulated any policy rationale for placing hemp seed and oil under Schedule I of the CSA, the companies submitting these comments are aware that the Office of National Drug Control Policy (“ONDCP”) has raised a concern that “the amount of THC in some hemp products is significant enough to cause positive drug tests. To maintain the integrity of the U.S. drug testing system, we cannot allow the legalization of products that may be consumed to contain THC.” Letter from Barry R. McCaffrey to Rep. John Shimkus, March 17, 2000; see also, Letter from Director McCaffrey to Hon. Michael J. Madigan, Feb. 28, 2000 (“individuals who tested positive for marijuana use subsequently raised their consumption of these food products [containing hemp seed] as a defense against positive drug tests”).

In fact, the relevant scientific evidence of which the Hemp Seed and Oil Products Companies are aware indicates that the food, body care and cosmetic products sold by these companies are not capable of causing confirmed positive test results in workplace drug tests if federal guidelines for testing procedures are followed. As noted, the Edible Hemp Products Companies distribute or use hemp seed imported from Canada or Europe typically containing less than 2 ppm THC and hemp oil imported from Canada or Europe typically containing less than 5 ppm THC.

The most recent reliable study of which the commenting Companies are aware is Leson, Pless, Grotenhermen, Kalant and ElSohly, "Evaluating the Impact of Hemp Food Consumption on Workplace Drug Tests," 25 Journal of Analytical Toxicology 691 (Nov./Dec. 2001), a copy of which is attached hereto as Exhibit 8. In this study, 15 adults ingested, over four successive 10-day periods, single daily THC doses ranging from 0.09 to 0.6 mg. These doses were selected to cover the conceivable range of THC intake from the repeated consumption of currently available hemp food products. Urine specimens were collected on days 9 and 10 of each of the four study periods and 1 and 3 days after the last ingestion. Specimens were screened by radioimmunoassay and confirmed for THC-COOH, the major THC metabolite in urine, by gas chromatography - mass spectrometry (GC-MS). None of the subjects who ingested daily does of 0.45 mg of THC screened positive at the 50-ng/mL cutoff. The highest THC-COOH level found in any of the specimens was 5.2 ng/ML, well below the 15-ng/ML confirmation cutoff used in federal drug testing programs. The study notes that "[c]urrently practiced seed cleaning methods appear to be successful in limiting THC concentrations in hemp oil and hulled seeds to 5 µg/g and 2 µg/g, respectively." Id. at 697. (µg/g is equivalent to parts per million, or ppm). The study concludes that, "adopting THC limits for hemp oil and seeds at the above levels and practicing routine GC-MS confirmation of urine specimens screening positive appear to minimize the risk of producing confirmed positive urine tests from hemp food consumption." Id. at 697.

A previous study had also confirmed that hemp seed and oil food products are now highly unlikely to cause false positives in drug testing. T. Bosy & K. Cole, "Consumption

and quantification of delta9-tetrahydrocannabinol available in hemp seed products,” 24 Journal of Analytical Toxicology 562 (2000). Hemp oils with THC levels ranging from 11.5 to 117.5 µg/g were used, from actual products being sold in the U.S in 1997, before the issue of THC in the products became generally known in the industry. Only at the highest dose which corresponded to THC concentrations no longer representative of current THC levels in hemp oil, were the screening cutoff of 50 ng/mL or the confirmation cutoff of 15 ng/mL exceeded.

The commenting companies are aware of earlier studies, which indicated the possibility that ingestion of foods containing hemp seed or oil could cause positive urine tests for marijuana. E.g., N. Fortner, R. Fogerson, D. Lindman, T. Iverse and D. Armbruster, “Marijuana-positive urine test results from consumption of Hemp seeds in food products,” 21 Journal of Analytical Toxicology 476 (1997); R. Struempfer, G. Nelson and F. Urry, “A positive Cannabinoids workplace drug test following the ingestion of commercially available Hemp seed oil,” 21 Journal of Analytical Toxicology 283 (1997). These studies, however, involved consumption of products made with seeds and oil containing up to 100 ppm of THC—far higher levels than are found in hemp seeds and oil used in the edible seed and oil, and edible products, now being sold in the U.S. Thus, current reliable research clearly indicates that edible hemp oil and seed, and hemp oil and seed products will not interfere with workplace drug testing programs for marijuana, particularly not if federal guidelines for confirmation by GC-MS are followed.

In this regard, the experience with potential interference of consumption of poppy seed with testing for morphine and codeine should be considered. A summary of the relevant literature is attached hereto as Exhibit 9. As this review demonstrates, initial studies established that poppy seeds contain trace elements of controlled substances, and further research showed that consuming poppy seeds produced measurable traces of controlled substances in urine. Additional research then focused on the effects of consuming realistic quantities of poppy seed food products and guidelines were established for ruling out poppy seed consumption as an explanation for opiate positive urinalysis results. Based on this newer research, the Department of Defense adjusted its drug-testing program to reduce the probability that poppy seed ingestion would trigger false positives. The threshold above which urine

samples were considered "confirmed positive" for opiates was raised by the Department of Health and Human Services in 1997-98 from 300 parts per billion (ppb) to 2000 ppb to address poppy seed consumption. 62 Fed. Reg. 51118-51120 (Sept. 30, 1997).

No adjustment in current testing protocols and thresholds is required to rule out hemp seed and oil, and seed and oil products, as a source of positive urine tests for marijuana. As the poppy seed example shows, however, even were such an adjustment necessary, the onus should be on the administrators of testing programs and the drug-testing industry, not on a legitimate non-drug food industry. For this reason, potential interference with drug testing does not provide any rationale for adding hemp oil and seed, and oil and seed products, to Schedule I of the CSA.

V. The Proposed Rule Would Have a Significant Impact on Small Business, Trade, Consumers, Farmers and Environmentalists

As noted above, the industry includes at least 20 U.S. and Canadian companies in the business of producing and distributing edible hemp seed and oil, and food, nutritional and beverage products made from hemp seed and oil. The Hemp Industries Association estimates that retail sales of these products through health food, natural foods and grocery stores exceed \$5 million annually, and that another \$1 million of these products are sold through restaurants, clubs and breweries. Trade statistics show that about 150 metric tons of whole hempseed, and 50 metric tons of shelled hempseed, were imported into the U.S. in 2000.

The U.S. market for hemp food products was virtually non-existent five years ago. Furthermore, these products have been carried by large natural foods retail chains only since 1999. This recent expansion of the market for hemp food products, combined with hemp seed and oil's exceptional nutritional and flavor profiles, indicate the considerable potential for further market growth, provided no regulatory restrictions to the trade in these products are imposed (much as the soy foods market started small twenty-five years ago with considerable growth potential).

DEA's "Interpretive Rule" has already threatened the survival of a number of companies in the U.S. and Canada. The monthly sales of Nutiva have dropped fifty percent and the company is behind in paying its creditors, jeopardizing its future. At Kenex Ltd., a major supplier of hemp seed and oil to the U.S., sales of hemp nut and hemp oil, previously accounting for fifty percent of the company's revenues, have virtually ceased. Hemp Oil Canada has suffered from the cancellation of three major orders for hemp oil and the company's ability to obtain financing has already been severely impacted. Obviously, other companies engaged in the production and distribution of hemp foods are suffering from a significant loss of business and will continue to suffer similarly severe impacts if the "Interpretive Rule" remains in place and/or the Proposed Rule is adopted.

Given the number of companies involved, the fact that they are virtually all small businesses and the scope of the sales involved, the commenting companies believe that the Proposed Rule will indeed have a significant detrimental impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. §605(b).

The DEA's Proposed Rule would also deprive a growing number of consumers in the U.S. of their access to an alternative source of dietary protein, essential fatty acids and micronutrients, as hemp seed and oil offer exceptional nutritional benefits relative to competing foods, particularly for observers of a vegetarian diet. DEA's Rules also eviscerate the efforts of environmentalists, farmers, and state lawmakers who have spent years to research, develop and commercialize hemp food and fiber products and create markets for such products.

In that regard it should be noted that, since the majority of ongoing ecological harm, according to the Union of Concerned Scientists, is caused by human activities in the areas of automobile production and transportation, meat and poultry production, agriculture, and home construction and maintenance, environmentalists engage in industrial hemp advocacy to encourage incorporation of industrial hemp as a non-toxic natural raw material into the design and manufacturing process for these industries, which substantially reduces the ecological

harm caused by these industries. Therefore, activities that promote industrial hemp and its markets, including food markets, can also promote ecological benefits and environmental sustainability. By restricting the use of industrial hemp, the Proposed Rule would have the effect of undermining those ecological benefits and progress towards environmental sustainability. As a result, the Proposed Rule could actually have the effect of harming the health, safety and wellbeing of the American people and their environment.

Farmers are concerned with industrial hemp because it fosters bioregional sustainability and the return to the possibility of a carbohydrate economy based on the notion that anything that can be made of a hydrocarbon (plastics, etc.) can be made from a carbohydrate. Petitioner Kenex's hemp fiber biocomposite products that are being used in the automotive industry are an example of farm grown biocomposite uses for hemp that bear out this vision

VI. The Interpretive and Proposed Rules Violate the NAFTA and WTO

In addition, the Interpretive and Proposed Rules would interfere with the free trade between the U.S. and Canada and would manifestly violate the NAFTA and WTO trade agreements. In publishing the Interpretive Rule and Proposed Rule, the DEA did not provide any meaningful opportunity for consultation with persons whose business would be immediately affected by those rules, including Canadian investors with investments in the territory of the U.S. and businesses engaged in the export of hemp food products from Canada into the U.S.

The DEA has provided no indication that it intends to similarly regulate any other food products that naturally contain trace, organic amounts of substances that are regulated under the CSA (i.e. poppy seeds containing trace opiates). In fact, poppy seeds are treated as competitive or substitutable with hemp food products in the USDA study, as is flax seed. USDA Study at 15-16.

On March 29, 2001, Bertin Coté, the Deputy Head of Mission for the Government of Canada's Embassy in Washington, D.C., wrote to DEA Administrator Donnie R. Marshall to express concern over the DEA's intention to subject virtually all hemp products containing trace amounts of organic tetrahydrocannabinols (THC) to regulation under the CSA. In particular, the DEA was asked to provide the Government of Canada with "all scientific and other relevant material used for the development, interpretation, and eventual implementation." It was also inquired how the DEA could conceivably impose a zero-THC standard and how the DEA intended to deal with other products that might contain trace amounts of psychotropic compounds, such as poppy seed products.

On May 9, 2001, Cynthia R. Ryan, the DEA's Chief Counsel, wrote to Minister Coté informing him that his request for information was "denied." Since then, the DEA has apparently not provided the Government of Canada any further response to its request of March 29, 2001, with respect to the rules it proposed and imposed on October 9, 2001.

As demonstrated above, the best scientific evidence available indicates that human consumption of the hemp food products that the DEA, through its Proposed Rule, would be subjecting to outright prohibition, does not result in discernable psychotropic effects or other undesirable health effects. Further, the best scientific evidence available demonstrates that hemp food products produced in compliance with the industry's "TestPledge" standards cannot result in confirmed positive urine tests for marijuana.

In Canada, the cultivation of industrial hemp is permitted only under strict regulatory licenses and authorizations, where leaves and flowering heads cannot contain more than 0.3 percent THC. The production, handling, manufacturing, marketing and trading of industrial hemp products in Canada also takes place under a strictly enforced regulatory regime. This regulatory regime is currently undergoing review by Health Canada, aimed at assessing and potentially improving its effectiveness in ensuring consumer protection. There is no evidence that the DEA has consulted, or cooperated, with the Government of Canada in seeking to achieve harmonization, equivalence, or even the coordination of Canadian and American regulatory standards and regimes with regard to hemp food products.

A. DEA's Interpretive and Proposed Rules Violate WTO Law

Numerous provisions of the General Agreement on Tariffs and Trade 1947 (GATT) and the WTO Agreement on Sanitary and Phyto-Sanitary Measures (SPS Agreement) appear to apply to the DEA's promulgation of the Interpretive and Proposed Rules. The GATT applies to measures affecting trade in goods. The SPS Agreement applies to measures, such as those imposed to protect human life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs, that directly or indirectly affect international trade.

The DEA's Interpretive and Proposed Rules purport to regulate trade in hemp food products, which are obviously "goods" within the meaning of the GATT. The DEA has ostensibly developed and imposed these rules to protect human life and health from trace amounts of THC contaminating hemp food products. Accordingly, the development and application of these measures is also governed under the SPS Agreement.

GATT Article XI:1 provides that Members shall not impose import prohibitions on any product from the territory of another Member. This includes *de facto* prohibitions such as the Interpretive Rule and the Proposed Rule. 1 Guide to GATT Law & Practice 315-17 (1995). Because the Interpretive Rule effectively prohibits all trade in hemp food products, it constitutes a breach of the U.S.'s obligations under GATT Article XI:1. Because the Proposed Rule will have an identical effect, it would also constitute a breach of GATT Article XI:1.

GATT Article III:4 provides that products of one member shall receive treatment no less favorable than that accorded to like products of national origin in respect of "all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use." GATT Article I:1 similarly provides that no less favorable treatment to like goods originating from other Members. 1 Guide to GATT Law & Practice, *supra*, at 197-198.

The findings presented by the USDA suggest that hemp food products are “like products” to food products containing poppy seed or flax seed. These products compete in the same markets. They are demarcated by similar consumer tastes and desires. By analogy to hemp food products, poppy seed products also contain trace amounts of substances (opiates) that are in themselves prohibited under the CSA, but are not controlled insofar as they are trace, non-active contaminants of the exempted poppy seed.

The WTO Appellate Body has recently reviewed the criteria that should generally be employed in determining whether goods are alike. It did so at para’s. 101-103 of EC – Measures Affecting Asbestos, WT/DS135/AB/R, March 12, 2001, indicating that four criteria, “or groupings of potentially shared characteristics,” have generally been used to determine likeness: “(i) the physical properties of the products; (ii) the extent to which the products are capable of serving the same or similar end-uses; (iii) the extent to which consumers perceive and treat the products as alternative means of performing particular functions in order to satisfy a particular want or demand; and (iv) the international classification of the products for tariff purposes.” Application of these criteria in this case appears to strongly indicate that hemp food products are very much “like” competing food products using poppy or flax seeds or oil.

Under the Interpretive Rule, hemp food products are prohibited from being produced or manufactured, by virtue of their improper addition to the CSA by the DEA, whereas like products from the U.S. or other countries are not subjected to any such regulation. Under the Proposed Rule, the same treatment will be maintained. Accordingly, GATT Articles III:2 and I:1 have been violated by the Interpretive Rule and will be violated by the Proposed Rule.

GATT Article XX provides a means of validating the application of measures that would otherwise breach a Member’s obligations under the GATT. There are two potential justifications for the Interpretive Rule and the Proposed Rule; however, it appears that neither is actually applicable. Paragraph (b) provides provisional justification for measures that are “necessary” to protect, among other things, human life or health. As demonstrated above in Section III of these comments, the U.S. will not be able to demonstrate that the Interpretive Rule or the Proposed Rule are “necessary” to protect human life or health.

Under GATT jurisprudence, a measure will normally be found to be “necessary” if it constitutes the least restrictive trade alternative available to the measure to protect human life or health. If a less restrictive alternative exists that is “reasonably available” for the Member to impose in order to meet its health objectives, such an alternative must be implemented instead of the impugned measure (this approach was recently reiterated and approved by the Appellate Body in EC – Asbestos, at para’s. 168-174). The DEA has yet to fully articulate the exact nature of the health or safety risks that it is attempting to address through its Interpretive Rule and Proposed Rule. Assuming that the risk in question is contamination by trace amounts of naturally-occurring THC in hemp food products, the existing Canadian regulatory regime demonstrates that a less trade restrictive alternative exists for the DEA to develop and impose, instead of an outright ban. Accordingly, it is not possible for the U.S. to justify the Interpretive and Proposed Rules under GATT Article XX(b).

GATT Article XX(d) permits a WTO Member to justify its measures as “necessary to secure compliance with laws or regulations which are not inconsistent with” any other GATT provisions. The U.S. could attempt to justify the Interpretive Rule and the Proposed Rule as being necessary to secure compliance with federal drug testing programs, which – in principle – should not violate a breach of any other GATT provision. However, there is no evidence that hemp food products which are produced in compliance with TestPledge standards interfere, in any way, with such programs. The very existence of the industry’s TestPledge program demonstrates that less trade restrictive means exist through which to deal with this issue. Also, as previously discussed, the U.S. government addressed poppy seed interference with opiate drug-testing by raising drug-testing thresholds for opiates in urine in the 1990’s, which is not necessary for marijuana testing as a TestPledge type governmental regulatory program of hemp seed and oil would be fully sufficient.

Accordingly, the Interpretive Rule most likely breaches Articles I:1, III:4 and XI:1 of the GATT, and cannot be justified under GATT Article XX. Because the Proposed Rule is designed to have the same legal effect as the Interpretive Rule, it will also violate Articles I:1, III:4 and XI:1 of the GATT, and cannot be justified under GATT Article XX.

Article 2:2 of the WTO SPS Agreement provides that SPS measures can only be applied to the extent that they are “necessary to protect human, animal or plant life or health;” that they are based upon “scientific principles;” and that they are “not maintained without scientific evidence.” As described above, neither the Interpretive Rule nor the Proposed Rule can be demonstrated as being necessary to protect human or animal life or health. The DEA has yet to provide any proof that its Rules are based upon any scientific evidence whatsoever, much less identified a specific risk for which such rules are considered necessary. Accordingly, the Interpretive Rule most likely violates Article 2:2 of the SPS Agreement and the Proposed Rule will most likely violate Article 2:2 of the SPS Agreement.

Moreover, Article 5:1 of the WTO SPS Agreement requires that SPS measures must be based upon a valid “risk assessment” process, which includes taking available scientific evidence into account (as indicated under Article 5:2) (In EU – Measures Concerning Meat Hormones and Meat Products, WT/DS26/AB/R & WT/DS48/AB/R, January 16, 1998, the WTO Appellate Body concluded, at para. 181, that Articles 2.2 and 5.1 of the SPS Agreement should “constantly be read together,” as “the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1.”). If a SPS measure is not “sufficiently supported or reasonably warranted by the risk assessment,” it will not be valid under Article 5:1 of the SPS Agreement. Id. at para. 186. In imposing its Interpretive Rule, the DEA has failed to take the available scientific evidence into account concerning hemp food products. If it continues to ignore the most relevant scientific evidence available concerning hemp food products, the DEA’s Proposed Rule will also likely violate Article 5:1 of the WTO SPS Agreement.

Article 5:4 of the WTO SPS Agreement requires that, in developing and imposing SPS measures, Members must take the objective of minimizing any negative trade effects of a measure into account. There is no evidence that the DEA has taken any steps to take this objective into account. Article 5:6 of the WTO SPS Agreement prohibits Members from establishing or maintaining SPS measures that are more trade restrictive than necessary to achieve the appropriate level of protection. As described above, the Rules put forward by the DEA on October 9, 2001 are far more restrictive than necessary to achieve an appropriate level

of protection from any risks to human life or health posed by trace amounts of THC in food products. Accordingly, the DEA's Rules constitute, and will constitute, a breach of Articles 5:4 and 5:6 of the SPS Agreement.

Article 5:5 of the WTO SPS Agreement requires Members to avoid arbitrary or unjustifiable distinctions in how the appropriate levels of protection that a Member chooses are applied in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. (The Appellate Body has determined that Article 5:5 "may be seen to be marking out and elaborating a particular route leading to the same destination set out in Article 2.3." *Id.* at para. 212.). As described above, even if it could be demonstrated that trace amounts of THC naturally occurring in hemp food products pose any kind of risk to human life or health (and that the DEA's Rules were therefore actually based on an acceptable risk assessment process), the DEA's Rules nonetheless constitute an arbitrary and unjustifiable distinction between appropriate levels of protection for hemp food products and food products containing poppy seeds with trace opiates. The result of the imposition of these Rules constitutes a disguised restriction on international trade and discrimination against hemp food products imported into the United States from Canada. (This analysis conforms to the three-part test enunciated by the Appellate Body in the EU – Beef Hormones case and reaffirmed in: Australia – Measures Affecting the Importation of Salmon, WT/DS18/AB/R, October 20, 1998, at pages 81-93. The Appellate Body also concluded that Article 2:3 could be presumed to have been violated by implication of a finding that a measure violated Article 5:5; and that a finding of inconsistency with Article 5:1 can provide a "warning sign" that may assist in establishing that a breach of Article 5:5 has also occurred.). Accordingly, the DEA's Interpretive Rule most likely breaches Article 5:5 of the SPS Agreement and its Proposed Rule will most likely breach Article 5:5 as well.

Finally, Article 5:8 of the WTO SPS Agreement requires the U.S. to provide an explanation to other Members if it maintains a SPS measure that is not based upon international standards, guidelines or recommendations and such a measure constrains trade in products affected by such a measure. The Government of Canada has been denied such an explanation by the DEA. Accordingly, the U.S. has failed to honor its obligation under Article

5:8 of the SPS Agreement to provide the Government of Canada with a sufficient explanation for its imposition of the Interpretive Rule and contemplated imposition of the Proposed Rule. Moreover, the U.S. has violated Article 7 of the SPS Agreement because it has failed to notify the Government of Canada of its imposition of the Interpretive Rule, or to provide the kind of information requested by the Government of Canada, and required to be provided, under Paragraph 7 of Annex B of the SPS Agreement.

B. DEA's Interpretive and Proposed Rules Violate NAFTA Law

In addition to sharing membership in the WTO, Canada and the U.S. are also Parties to the most extensive regional free trade agreement in the world: the NAFTA. The NAFTA contains many provisions that are similar to GATT and WTO SPS obligations. It also contains provisions that incorporate GATT obligations by reference. Accordingly, a breach of various GATT provisions also constitutes a breach of certain NAFTA obligations.

The NAFTA also includes investment obligations that do not exist under the WTO framework. These investment obligations are relevant for this analysis, however, because it appears that certain members of the Canadian hemp food industry have investments in the territory of the U.S. (including Canadian “Edible Hemp Products Companies”), or had investment plans, that have been negatively affected by the Interpretive Rule and would be negatively affected by the Proposed Rule. If these Investors can demonstrate that they have suffered a loss due to the impact of these Rules, and that these rules breach a substantive provision of NAFTA Chapter 11, the U.S. could be liable to pay damages to fully compensate them for their losses. Moreover, Canada needs only to demonstrate that such breaches exist for it to take action under NAFTA Chapter 20, regardless of whether a loss has even occurred.

The Interpretive Rule most likely violates NAFTA Article 309(1) because it most likely violates GATT Article XI(I). It most likely violates NAFTA Article 301(1) because it most likely violates GATT Article III. The Proposed Rule will most likely violate NAFTA Article 309(1) because it will most likely violate GATT Article XI(I). It will most likely violate NAFTA Article 301(1) because it will most likely violate GATT Article III. Neither Rule can

be saved under NAFTA Article 2101(1)(a) because they cannot be saved under GATT Article XX.

The NAFTA contains an SPS chapter that is very similar to the WTO SPS Agreement. NAFTA Article 712(3) requires SPS measures to be based upon scientific principles and an acceptable form of risk assessment process. Under NAFTA Article 715(1), such risk assessment must include: (b) relevant scientific evidence; and (c) relevant process and production methods. As described above, neither the Interpretive Rule nor the Proposed Rule appear to be based upon a risk analysis, including the relevant scientific evidence, which would demonstrate that hemp food products in fact pose a risk to human health or safety.

NAFTA Article 712(4) prevents the U.S. from imposing SPS measures that constitute arbitrary discrimination or unjustifiable discrimination against Canadian hemp products, as compared to like products such as those based upon poppy seed or flax seed. As described above, the Interpretive Rule and the Proposed Rule are therefore likely to breach NAFTA Article 712(4). NAFTA Article 712(5) requires the U.S. to refrain from imposing SPS measures that are not necessary to achieve an appropriate level of protection. As described above, even if the U.S. could demonstrate, based upon relevant scientific evidence, that there is any risk in consumption of hemp food products (and that it had employed a valid risk assessment in imposing either its Interpretive Rule and its Proposed Rule), it would also need to demonstrate that its outright ban is necessary to address such risk. Accordingly, it is most likely that the Interpretive Rule and the Proposed Rule will violate NAFTA Article 712(5).

Further, because the U.S. has made no effort whatsoever to seek, much less achieve, regulatory equivalence with Canada's stringent regulatory regime and standards for the production of hemp food products, the Interpretive Rule most likely violates (and the Proposed Rule will most likely violate) NAFTA Articles 714(2)(a) and 714(4), which require such an effort to be made.

The U.S. appears to have already violated NAFTA Article 714(2)(c), because the DEA has refused a request from the Government of Canada to provide its reasons, in writing, for not

explaining why it cannot adopt Canada's stringent standards on hemp food production, to achieve whatever its SPS objectives actually are, including any scientific basis for not doing so. Moreover, as the United States has refused to comply with the request of the Government of Canada to be provided with relevant scientific evidence and the DEA's rationale for imposing the Interpretive Rule and the Proposed Rule, it has likely already violated its obligation not to do so under Article 1803(2).

Further, the U.S. has most likely already violated NAFTA Article 715(3) because, in choosing the appropriate level of protection for any SPS risks involved in the production of hemp food products, the United States has: (a) not taken into account the objective of minimizing negative trade effects; and (b) failed to avoid creating arbitrary or unjustifiable distinctions between its treatment of hemp food products and products such as those based upon poppy or flax seed.

In addition to the obligations owed by the U.S. to Canada under both the WTO Agreement and the NAFTA, the U.S. may additionally owe an obligation to compensate various members of the hemp industry for losses arising from the imposition of the Interpretive Rule and the Proposed Rule on their investments in the territory of the U.S.. This obligation is owed under NAFTA Articles 1116 and 1122, through which the U.S. has agreed to pay compensation for such losses if they arise out of a measure that breaches certain provisions of NAFTA Chapter 11.

Under NAFTA Articles 1102, 1103 and 1104 the U.S. must abstain from imposing measures that provide more favorable treatment to any local or foreign competitor of NAFTA investors or their investments in the territory of the U.S. without a valid policy reason. (This analysis has been employed by three NAFTA tribunals considering NAFTA Article 1102. The same conclusions can be drawn about NAFTA Article 1103, which contains the same structure as NAFTA Article 1102, with the comparator merely changed from local competitors to other foreign competitors. NAFTA Article 1104 simply guarantees the better of treatment required under NAFTA Articles 1102 and 1103. The most complete analysis of these provisions thus far has been provided by the Tribunal in: Re: Pope & Talbot, Inc. and the Government of

Canada, Final Merits Award, NAFTA/UNCITRAL Tribunal, April 10, 2001, at para's. 39-42 & 71-81.). The Interpretive Rule and Proposed Rule provide better treatment to all of the local and foreign competitors of Canadian hemp industry members with investments, or intentions to invest, in the territory of the U.S.. These competitors receive better treatment because they make competing food products using poppy or flax seeds and oil, rather than hemp seeds and oil, and these competing products are not banned from commerce, as have been hemp food products under the Interpretive Rule and the Proposed Rule.

The DEA has provided no reasonable policy justification for imposition of a total ban on hemp food products while not similarly banning the products of competitors. In fact, it has provided no reasonable policy justification for banning hemp food products at all. Even if it could be assumed that competitors using flax seed in their products are not in like circumstances with hemp food producers because flax contains no trace amounts of psychotropic chemicals, competitors using poppy seeds cannot be similarly differentiated.

Finally, the U.S. is obligated under NAFTA Article 1105 to providing treatment to the investments of Canadian hemp food industry members operating in the United States that is "fair and equitable" and otherwise not less than that which is required under international law. Under this provision, the DEA must not treat the investments of Canadian hemp industry members in an arbitrary or unreasonable manner and it must not fail to honor its other international obligations in the process of imposing such measures if they result in harm to the investment. (On July 31, 2001, the NAFTA Free Trade Commission issued a purported "interpretation" of NAFTA Article 1105 that would limit it to requiring the U.S. to provide "fair and equitable treatment" in accordance with the customary international law minimum standard of treatment. However, under NAFTA Article 1103 and NAFTA Article 102(1), NAFTA Article 1105 must be interpreted in light of the "most favored nation" (MFN) principle. Application of the MFN principle to Article 1105 requires an interpreter to require the U.S. to provide no less than the same level of treatment it accords to any other investors under any other foreign investment treaty signed since the NAFTA came into force in 1994. Numerous bilateral investment treaties concluded between the U.S. and third countries contain "minimum standard" provisions that require "fair and equitable" treatment that in no case falls

below that which is required under international law. They also contain prohibitions against “unreasonable” or “discriminatory” measures that impair “the management, conduct, operation, and sale or other disposition of” investments. Accordingly, these are the standards to which the U.S. would be held accountable under a NAFTA claim).

The very suggestion that the DEA would need to supplement its Interpretive Rule with the Proposed Rule suggests that the DEA is well aware that its interpretation is not a valid exercise of its discretion. The DEA may similarly be aware that its Rules will most likely violate its international treaty obligations (under the NAFTA and WTO) in myriad ways. Documents obtained by hemp industry members under the federal Freedom of Information Act (FOIA) indicate that DEA officials were well aware that such a course of conduct would likely breach the international treaty obligations of the United States. Under the international law principle of good faith, the U.S. is obliged to honor its international treaty obligations, and not to exercise its discretion in an abusive manner.

DEA has arbitrarily imposed a measure (the Interpretive Rule) that unreasonably impairs the investments of Canadian hemp industry investors in the territory of the U.S., and it appears to have done so in a non-transparent manner. The Proposed Rule would entrench this measure, and the arbitrary and unreasonable manner in which it has interfered with such investments. These measures are accordingly likely to be found to breach the standard of “fair and equitable” treatment required under NAFTA Article 1105. (The Interpretive Rule and the Proposed Rule constitute such an arbitrary and unreasonable interference with the investments of Canadian investors that it constitutes a breach of the customary international law minimum standard of treatment, as reflected in the “fair and equitable” treatment standard that can be found in thousands of bilateral investment treaties, and which is reflected in the regulatory standards agreed upon by a majority of the world community through countless multilateral trade treaty obligations. Such a finding would even meet the interpretation of NAFTA Article 1105 provided by the NAFTA Free Trade Commission in its July 31, 2001 statement).

With its promulgation of the Interpretive Rule and the Proposed Rule, and its refusal to provide documents and an explanation for these measures to the Government of Canada, the

DEA has violated a number of international economic treaty obligations. If the Interpretive Rule is maintained and the Proposed Rule is put into force, the U.S. will run the very real risk of WTO and NAFTA liability, as well as the additional challenge of successful investor-state claims from NAFTA investors adversely affected by these measures.

CONCLUSION

For the reasons set forth above, the Proposed Rule should not be adopted. To the extent DEA wishes to add hemp oil and seed, and oil and seed products, to Schedule I of the CSA, a formal rulemaking proceeding should be conducted. In any event, it is clear that even if such a proceeding were conducted, DEA could not lawfully add these products to Schedule I.

Thus DEA has no authority to regulate hemp seed and oil, and oil and seed products. DEA should therefore abandon its effort to ban the legitimate manufacture, importation, distribution, and consumption of hemp food products. To the extent any regulation is called for, FDA, not DEA, is the appropriate agency to develop and implement such regulation.

Respectfully submitted,

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