Sandler, Reiff & Young, P.C.
6 E St. SE
Washington, DC 20003

February 16, 2001

Honorable Donnie Marshall, Administrator
Drug Enforcement Administration
7000 Army-Navy Drive
Arlington, VA 22202

Re: Planned Interpretive and Interim Rules Affecting Hemp Seed & Oil Products

Dear Administrator Marshall:

We are writing on behalf of a group of companies that have collectively invested millions of dollars and several years to develop, produce, market and sell, in the United States, personal care, cosmetic and/or food products containing processed hemp seed or oil, which in turn may contain non-psychoactive miniscule trace amounts of naturally-occurring tetrahydrocannabinols ("THC"), which are not currently a controlled substance. The DEA has announced its plans to publish three rules—an interpretive rule, an interim rule and a proposed rule—which would effectively outlaw the manufacture and sale of these products. Department of Justice Regulatory Agenda, 65 Fed. Reg. 74004, 74025 (Nov. 30, 2000). Presumably, the interpretive and interim rules would be issued without any notice and opportunity for comment, and without following the procedures set forth in the Controlled Substances Act ("CSA"), and the Administrative Procedure Act ("APA"), for adding substances to schedules established by the CSA. The subject companies ("Hemp Seed and Oil Products Companies") submit that the interpretive and interim rules should not be issued because their issuance would be contrary to law. If DEA proposes to outlaw products containing hemp seed and oil, it must conduct a formal rulemaking proceeding to do so.[1]

The Hemp Seed and Oil Products Companies recognize the law enforcement objectives sought to be achieved by DEA. These companies, however, are justifiably

[1] This submission does not address the extent to which the planned rules may trigger U.S. obligations or liability under NAFTA and other international trade agreements by reason of the banning of the importation of hemp seed and oil from Canada and the EU.

concerned that their production and sale of commercially successful and currently legal personal care, cosmetic and food products will be suddenly outlawed without any opportunity to develop, through appropriate rulemaking procedures, regulations that will serve legitimate law enforcement objectives without shutting down or over-regulating a legitimate industry, resulting in the loss of businesses and jobs.

SUMMARY

Non-psychoactive hemp seed and oil containing trace amounts of naturally-occurring THC are not currently, nor have they ever been, treated as controlled substances under the Controlled Substances Act, 21 U.S.C. §§802 et seq. ("CSA"). Imposing such treatment—i.e., adding hemp seed and oil with naturally occurring THC to any of the CSA schedules-- requires a formal rulemaking on the record pursuant to the requirements of the CSA, 21 U.S.C. §811(a) and the Administrative Procedure Act, 5 U.S.C. §§ 556 & 557 ("APA").

In the planned interpretive rule, DEA would "interpret" the CSA "such that any substance containing any amount of THC is a Schedule I controlled substance—even if such substance is made from 'hemp.'" Regulatory Agenda, supra, 65 Fed. Reg. at 74025. To the extent such an interpretation results in the classification of hemp seed and/or oil as controlled substances, it would effectively outlaw legitimate food and cosmetic products, the manufacture and sale of which are now perfectly lawful. Such an interpretation would represent an exercise of powers by DEA outside of the agency's delegated authority to add substances to the CSA schedules through a formal rulemaking process. The interpretation would substantially impact the rights of an entire industry and its customers and, therefore, clearly would have substantive, legislative effect. Such action may also amount to an unconstitutional taking without due process of law. For those reasons, the planned rule cannot lawfully be issued as an "interpretive" rule but, rather, must be subject to a formal rulemaking proceeding in accordance with the CSA and APA.

Similarly, the planned interim rule would attempt to exempt hemp fiber products from the CSA and DEA regulations but would outlaw "'hemp' products that result in THC entering the human body." Regulatory Agenda, supra, 65 Fed. Reg. at 74025. It appears that the interim rule would outlaw legitimate hemp seed and oil food, cosmetic and body care products containing any amount whatsoever of naturally-occurring THC, even at levels incapable of producing any psychoactive effect or other undesirable effects. Under the APA, DEA may not take such action without a rulemaking proceeding and a delayed effective date unless DEA can, for "good cause," find that notice and comment procedures are "impracticable, unnecessary or contrary to the public interest." 5 U.S.C. §553(b)(B).

Despite the invocation of "public health and safety" in the Regulatory Agenda announcement, there is no "good cause" for dispensing with the required formal rulemaking procedures in any effort that would result in outlawing legitimate hemp seed and oil products. "Good cause" for not following APA requirements exists only in the presence of a true emergency—an imminent, broad threat to public safety or health. The relevant scientific research reviewed by the Hemp Seed and Oil Products Companies indicates that use of body care and cosmetic products, and 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. Further, the most reliable scientific research of which the companies are aware indicates that neither the use of body care and cosmetic products containing such hemp oil, nor the consumption of food products containing such hemp seed or oil, even in amounts vastly exceeding normal use, can possibly have any psychoactive effect or any ill effects on human physiology or health.

In short, no public health or safety emergency exists to support the issuance of an interim rule. Even where scientific evidence may not be conclusive, the very existence of scientific controversy requires full public scrutiny on the record after the opportunity for a hearing, before any new regulation can be issued. For these reasons, there is no lawful

basis for DEA to dispense with the required rulemaking procedures in promulgating rules that would effectively outlaw the production and sale of food and cosmetic products made with hemp seed and oil.

The Hemp Seed and Oil Products Companies on whose behalf this submission is made include:

Atlas Corporation, Culver City, California

BioHemp Technologies, Regina, Saskatchewan, Canada

The Body Shop, Wake Forest, North Carolina

Chi Hemp Industries Inc. & Zima Foods Inc., Victoria, British Columbia, Canada

Dr. Bronner's Magic Soaps, Inc., Escondido, California

Fresh Hemp Foods Ltd., Winnipeg, Manitoba, Canada

Hemp Oil Canada, Inc., Ste. Agathe, Manitoba, Canada

Hempola, Inc. and Hempola Valley Farms, Ltd., Barrie, Ontario, Canada

Kenex, Ltd., Chatham, Ontario, Canada

The Merry Hempsters, Inc., Eugene, Oregon

Ohio Hempery, Inc., Guysville, Ohio

R&D Hemp, Inc., Toronto, Ontario, Canada

Santa Barbara Hemp Company, Santa Barbara, California

Sue's Amazing Lip Stuff, Inc., Westby, Wisconsin

Tierra Madre, LLC, Lexington, Kentucky

Two Star Dog, Berkeley, California

Virgin Body Care, Inc., Cedar Rapids, Iowa

Hemp Industries Association, Occidental, California

DISCUSSION

I. Background: The Hemp Seed and Oil Products Industry

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 medicinal 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 (see section II, infra) enabled US 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. 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 a nut. Seeds are separated and cleaned; oil is extracted through a 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 16.

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. Geiwitz, "THC in Hemp Foods and Cosmetics: The Appropriate Risk Assessment" (2001). Dr. Udo Erasmus, an internationally recognized authority on the subject of oils and fats, writes in Fats that Heal – Fats that Kill: "Hemp seed oil may be nature's most perfectly balanced oil. It contains an ideal 3:1 ratio of omega-6's [linoleic acid] to omega-3's [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. Consuming hulled hemp seed blended in shakes or drink mixes is an excellent way to meet 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).

The USDA Study also finds that hemp oil is sold as a nutritional supplement because of its content of linoleic and alpha-linolenic acids, and gamma-linolenic acid. Kentucky Study at 17. Encapsulated hemp seed oil supplements are found in natural foods markets, usually next to increasingly popular flax supplements. The presence of the rare fatty acid, gamma-linolenic acid (GLA), is a primary reason for the purchase of hemp oil as a nutritional supplement, together with borage and evening primrose oil.

Hemp meal, the seedcake remaining from the oil crush, contains a large fraction of protein, with a composition similar to that of soy. The market for high protein powders and flours for use in shakes, energy bars, baking preparations, etc. is well established. Hemp's naturally nutty flavor complements the fruit, nut and chocolate ingredients normally used in these products.

The EFA's that make hemp oil valuable as a food ingredient also make it ideal as a topical ingredient for the skin in cosmetic formulations. As the USDA Study notes, one of the key current uses of hemp oil is "for body care products, such as lotions, moisturizers, shampoos and lip balms." USDA Study at 17. The high EFA content of hemp oil soothes, restores and moisturizes skin better than many other plant based oils. These EFA's "work directly on epidermal cells, entering the lipid layers of dry skin cells to replenish their oils." Geiwtiz, supra, at 23. "Shampoos and skin care products are one of the most promising groups of products made from industrial hemp grain oils." See Kentucky Study at 7. Since the introduction of The Body Shop's line of hemp based body lotion, hand cream, soap and lip conditioner to the global marketplace, demand for hemp oil has grown rapidly, and many other cosmetic companies have introduced hemp oil based lines.

A chart from the USDA Study summarizing the use of hemp seed and oil in processed products is attached to this submission as Exhibit 1.

The companies currently selling hemp seed and oil food, body care and cosmetic products in the U.S. generally either import hemp seed and oil from Canada or Europe for use in manufacturing products domestically, or import already finished products from Canada or Europe. These products represent a complete chain of production from farmers' fields to retail shelves and consumers' homes. The Hemp Seed and Oil Products Companies making this submission include the following:

Atlas Corporation is an import/export trading company handling, among other commodities, refined and unrefined hemp seed oil which it imports from Canada and Europe. The oil is sold through distributors and directly to manufacturers of cosmetic products and nutritional supplements whose products are distributed throughout North America and Europe. Annual sales of hemp seed products total approximately $500,000 on a wholesale basis. Bulk oil, once imported, is stored and shipped from various locations in the greater New York and Los Angeles areas. Atlas is based in Culver City, California.

BioHemp Technologies, based in Regina, Saskatchewan, Canada, is a contractor and marketer of value-added hemp products derived from hemp grain. These products include certified organic and conventional hempseed oil, dehulled hempseed, toasted hempseed, hempseed flour and seedcake. The company's products are used for food, feed and cosmetic applications. BioHemp also markets a line of products named Mum's Original, which is sold in over 200 locations in Canada and in 10 U.S. locations. Mum's has been on the market for 7 months. BioHemp expects to sell $200,000 plus of its products into the U.S. in 2001, and currently employs 2 full-time employees and contracts 11 sales representatives.

The Body Shop is a high-quality skin and hair care retailer and manufacturer operating in 49 countries with around 1800 outlets spanning 29 languages and 12 time-zones. The company is not simply a manufacturer and retailer of toiletries and cosmetics, but is also committed to environmental protection and respect for human rights; it has developed trading relationships with communities in need; is against animal testing in the cosmetics industry; and encourages education, awareness and involvement among its staff and customers. The Body Shop US would suffer damages in excess of $5.9 million should any regulations be issued which would have the effect of banning or restricting the markets for hemp oils.

Chi Hemp Industries Inc. (CHII) & Zima Foods Inc.: CHII distributes certified organic hemp seed oil to individuals and bulk conventional hemp seed to brew

houses in the U.S. Zima Foods manufactures in Canada an organic hemp seed carob bar called the Zima Crisp sold throughout the U.S. Sales in the U.S. are $100,000 plus annually. The companies have 6 employees and the products are packed and shipped from Victoria and Vancouver, British Columbia, Canada.

Dr. Bronner's Magic Soaps sells liquid and bar soaps containing hemp oil, which the company obtains from Canada and Europe. The hemp soaps are distributed throughout the U.S. and annual retail sales are approximately $15 million. The soaps are manufactured in the U.S. and are packed and shipped from Escondido, CA. The company employs approximately 18 people.

Fresh Hemp Foods Ltd. is a grower and processor of hemp seed for use in manufacturing its own hemp seed oil and hemp food products. The products are manufactured in Canada, packed and shipped from Winnepeg, Manitoba and distributed throughout Canada, Europe and the U.S. The company sells annually $1,000,000.00 at retail and employs 9 people.

Hemp Oil Canada, Inc. is a producer of hemp seed and processor of bulk hemp food and vitamin supplement products including hemp seed oil, hemp oil gelcaps, toasted and roasted hemp seed, hulled hemp seed, cracked hemp seed and sterilized hemp seed. The company has developed and distributes a retail brand of hemp food, vitamin supplement and body care products including hemp seed oil, gelcaps, hulled hemp seed, toasted hemp seeds, hemp coffee, hemp flour, hemp protein powder and hemp shampoo, conditioner, hand lotion, massage and bath oil, moisturizing cream, lip balms, hand soap and mosquito repellent. The company's products are manufactured in Canada and distributed worldwide, with the U.S. market presently making up about 75% of its bulk production and 40% of its retail brand sales. The bulk hemp food production is marketed to U.S. food manufacturers, and used to produce food products ranging from bottled hemp seed oil, hemp cereal, hemp candy bars, hemp butters and spreads, to hemp coffee and hemp beer. The company is based in Ste. Agathe, Manitoba, Canada.

Hempola, Inc. and Hempola Valley Farms, Ltd. are Canadian companies involved in growing and processing hemp and in the development of hemp products, in particular hemp grain. The companies' products are manufactured in Canada and distributed throughout Canada, the U.S. and other countries. The companies are based out of Barrie, Ontario, Canada and revenues for the last fiscal year totaled about $11.1 million.

Kenex, Ltd. has invested five years and several million dollars to develop and commercialize industrial hemp food and fiber; 95% of its market is in the U.S. The company produces hemp oil, certified seeds, hempnut (grain) and fiber products; its annual sales of hemp oil and hempnut grain exceed $1 million. The firm's principal place of business is in Ontario, Canada; it maintains a Delaware subsidiary for marketing its products.

The Merry Hempsters, Inc. produces a variety of herbal medicinal and body care products using a certified organic hemp seed oil base. The company's lip balms are made with as much as 70% hemp oil. The company imports hemp seed oil from Canada. It sells its products throughout the U.S; estimated retail sales totaled approximately $1 million in 2000. The company produces its products in Eugene, Oregon, and employs up to 13 people.

Ohio Hempery, Inc. distributes hemp seed and oil products in the U.S., and its sales are about $300,000 per year. The company is the oldest continuous hemp business in the U.S., and is based in Guysville, Ohio.

R&D Hemp, Inc. manufactures and sells hemp raw materials, namely hemp oil and hemp flour, which is obtained from hemp seed grown specifically for the company. These raw materials are incorporated into hemp products both domestically and abroad. R&D Hemp has exported from Canada approximately 5000 kilos (11,000 lbs) of oil annually in the past, and expects their oil sales to double in 2001, and anticipates further sales of 24,000 lbs of hemp flour. The company is based in Toronto, Ontario, Canada.

Santa Barbara Hemp Company maintains a retail store in Santa Barbara, California, selling a full line of hemp seed food and body care products, purchased from U.S. distributors.

Sue's Amazing Lip Stuff, Inc. manufactures a line of personal care products, including soap, shampoo, conditioner, lip balm, hand cakes, lotion, liquid soap and body crème, using hemp oil imported from Germany and Canada. The company's annual sales are about $900,000; it has 12 employees at its facility in Westby, Wisconsin.

Tierra Madre LLC has invested more than $2 million since 1997 to develop and commercialize industrial hemp food and fiber products directly and through its Canadian trading partners, Kenex, Ltd., Industrial Hemp Seed Development Company and Hemp Oil Canada, Inc. Among other things, Tierra Madre has spent two years and more than $100,000 to develop Hempmylk™, a nondairy beverage similar to soymilk, which is now subject to a product rollout and nationwide distribution. Tierra's Hempmylk™ product is manufactured in Oregon by a licensed producer/co-packer using imported Canadian hempnuts and shipped from Oregon to distribution points in the U.S. Tierra's principal place of business is in Lexington, Kentucky. Tierra Madre estimates that it would suffer losses in excess of $2 million if the U.S. market for hemp oil and seed products is restricted by the proposed DEA regulations or otherwise.

Two Star Dog, based in Berkeley, California, has marketed and sold a line of body care products throughout the U.S. since 1997. The company employs more than 40 people and its annual sales exceed $3 million, a significant portion of which are the hemp oil-based body care products.

Virgin Body Care, Inc. manufactures a full line of body care products using hemp oil imported from Canada, the United Kingdom and Germany. The company's annual sales total $1.8 million; it employs 9 people at its facility in Cedar Rapids, Iowa.

This submission is also endorsed by the **Hemp Industries Association**, a trade association dedicated to education, industry development and accelerating expansion in the hemp supply and world market demand. HIA, based in Occidental, California, has 285 members.

II. Current Law

Industrial hemp plants grown in Canada and Europe are bred to contain less than three-tenths of one percent (< 0.3%) THC in the upper portion of the flowering plant. USDA Study at 7. The hemp seed (or nut) itself contains only minute traces of THC, usually much less than 0.5 parts per million (ppm) of THC; however "[d]epending on the hemp variety and the degree of seed cleaning, various amounts of THC residues can be found on the outer shells of whole seed and in the products made from hemp seeds." Leson & Pless, "Evaluating Interference of THC In Hemp Food Products with Employee Drug Testing" 2 (2000). Hemp oil may contain trace amounts of THC from 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). Currently, THC levels in hulled seeds produced in Canada are typically less than 2 ppm and in hemp seed oil, less than 5 ppm. Leson & Pless, supra.

Although the CSA does not recognize any distinction between drug-cannabis (with psychoactive concentrations of THC) and non-drug industrial hemp (with no psychoactive THC concentrations and not usable as a drug), such a distinction has been established by the laws of other nations and has been recognized in the markets that have supported the growth of industrial hemp as a commercial crop and industry. The development of this crop and these markets has led Canada and the European Union to adopt clear regulations enabling legitimate businesses and farmers to manufacture and trade in industrial hemp products such as the hemp seed and oil products now at issue, while also addressing legitimate law enforcement concerns. In the United States, legislation relating to industrial hemp has been enacted in sixteen states and the National

Conference of State Legislatures has adopted a resolution calling upon Congress to distinguish between industrial hemp and drug cannabis.

The CSA currently 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, notwithstanding low THC content. Id.

The 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. In fact, the express exclusion of hemp oil, cake and sterilized seed was adopted by Congress in order to make clear that its intention was only to regulate drug-cannabis and that it did not intend to interfere with legitimate hemp industry. See, e.g., 81 Cong. Rec. App. 1440 (1937); Taxation of Marihuana, Hearings before the Comm. on Ways and Means on H.R. 6385, 75th Cong., 1st Sess. 1, 43, 46-47, 53-54, 67-71. The Hemp Seed and Oil Products Companies have developed their products and made significant investments in reliance on this statutory exclusion.

Schedule I(c)(17), covers "any material, compound, mixture or preparation, which contains any quantity of" THC. DEA's regulations 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). "THC", as used in CSA Schedule I, does not refer to organic, naturally-occurring THC such as that found in hemp oil, cake and sterilized seed, but only to synthetic THC. This construction was recognized in United States v. McMahon, 861 F.2d 8 (1st Cir. 1988). In that case, the Court of Appeals found that hashish and sea-hash were controlled only by Schedule I(c)(1) as "marihuana" (as a derivative of the resin) and not by Schedule I(c)(17), because "the substance referred to in Schedule I(c)(17) is synthetic, not organic THC." 861 F.2d at 11. Similarly, in United States v. Wuco, 535 F.2d 1200 (9th Cir. 1976), the Court of Appeals explained that "organic THC . . . is not the synthetic THC defined as a Schedule I controlled substance." Id. at 1202. It is clear from the statutory language of the CSA that "THC" as set forth in CSA Schedule I does not include the minute trace organic THC occurring in non-psychoactive hemp oil, cake and sterilized seed.

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. In a letter to you dated March 23, 2000, John Roth, Chief of the Narcotic and Dangerous Drug Section of the Criminal Division, 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).

An identical letter, dated March 22, 2000, was sent by Mr. Roth to U.S. Customs Commissioner Raymond W. Kelley.

It is clear that hemp oil, cake and sterilized seed containing trace amounts of THC are not currently, nor have they ever been, treated as a controlled substance on any schedule of the CSA or in any other law.

III. Scheduling Hemp Oil, Cake and Sterilized Seed Requires Formal Rulemaking

The Administrative Procedure Act, 5 U.S.C. §553, 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.

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). 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).

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). 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). To add a new substance to a CSA schedule, the DEA must undertake a formal rulemaking process.

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. In addition, the agency would be required to comply with section 553(d), requiring that a new rule be published at least 30 days before its effective date.

Furthermore, 21 U.S.C. §811(b) requires that: "The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug . . . request from the Secretary [of HHS] a scientific and medical evaluation, and his recommendation as to whether such drug . . . should be so controlled . . . as a controlled substance."

IV. The Planned "Interpretive" Rule Is Legally a Substantive Rule That Must Be Issued Through a Rulemaking Procedure

Under section 553(b)(A) of the APA, "interpretive" rules are exempt from notice and comment rulemaking requirements. DEA's planned "interpretive" rule, however, is in fact a substantive, legislative rule, issuance of which requires that notice and comment rulemaking procedures be followed.

The exceptions to APA's requirements for notice and comment are to be "narrowly construed and only reluctantly countenanced." Alcaraz v. Block, 746 F.2d 593, 612 (D.C. Cir. 1984). "It is well-established that an agency may not escape the notice and comment requirements. . . by labeling a major substantive legal addition to a rule a mere interpretation." Appalachian Power Co. v. EPA, 208 F.3d 1015, 1024 (D.C. Cir. 2000). The agency's own label is not dispositive; "we do not classify a rule as interpretive just because the agency says it is." Chamber of Commerce v. OSHA, 636 F.2d 464, 468 (D.C. Cir. 1980).

The distinction between "interpretive" and "substantive" rules is well-established. "Substantive rules are ones which 'grant rights, impose obligations, or produce other significant effects on private interests,". . . or which 'effect a change in existing law or policy.'" American Hospital Association v. Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987), quoting Batterton v. Marshall, 648 F.2d 694, 701-02 (D.C. Cir. 1980) and Alcaraz, supra, 746 F.2d at 613. "Interpretive rules, by contrast, 'are those which merely clarify or explain existing law or regulations, . . . are 'essentially hortatory and instructional,' . . . and 'do not have the full force and effect of a substantive rule but [are] in the form of an explanation of particular terms.'" American Hospital Association, 834 F.2d at 1045, quoting Alcaraz, supra, 746 F.2d at 613 and Gibson Wine Co. v. Snyder, 194 F.2d 329 (D.C. Cir. 1952).

In American Mining Congress v. Mine Safety & Health Admin., 995 F.2d 1006 (D.C. Cir. 1993), the D.C. Circuit identified four factors, any one of which, if present, indicates that a supposed interpretive rule is actually a legislative one:

> (1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule.

995 F. 2d at 1112.

It is manifest that, to the extent it would render unlawful the currently lawful production and sale of products containing hemp oil, cake and sterilized seed, the planned "interpretive" rule in fact "imposes obligations" and "produces other significant effects on private interests." American Hospital Association, supra, 834 F.2d at 1045. It would ban the production and sale of the products currently imported, produced and/or sold in the U.S. by the Hemp Seed and Oil Products Companies.

Further, the purported "interpretive" rule would clearly work "a change in existing law or policy." Id. At least two of the American Mining factors are obviously present. First, "in the absence of the rule, there would not be an adequate legislative basis for enforcement action." As the Department of Justice Criminal Division confirmed in Mr. Roth's letter, there exists no current legal basis for banning the importation or sale of hemp products containing trace amounts of THC. The "interpretive" rule would supply such a basis and thereby be a legislative rule. See Chrysler Corp. v. Brown, 441 U.S. 281, 203-03 (1979).

Second, the rule "effectively amends a prior legislative rule." Hemp oil, cake and sterilized seed containing trace amounts of THC are not currently covered by any CSA schedule but rather were expressly excluded from the definition of "Marihuana," a statutory exclusion upon which the Hemp Seed and Oil Products Companies have reasonably relied in investing millions of dollars to develop and market their products. As a result of the "interpretive" rule, such materials would be covered by Schedule I. The "interpretive" rule would add a new substance to a CSA schedule. It is difficult to imagine a clearer case of amending a prior rule. For these reasons, the "interpretive" rule is, in legal contemplation, a substantive one.

In Syncor Int'l Corp. v. Shalala, 127 F.3d 90 (D.C. Cir. 1997), the Food and Drug Administration issued an announcement that positron emission topography radiopharmaceuticals should be regulated as a drug under the Federal Food, Drug and Cosmetic Act. FDA claimed that the announcement was an "interpretive" rule. The Court of Appeals disagreed, holding that the "crucial distinction" between an interpretive

rule and a substantive rule is that "a substantive rule modifies or adds to a legal norm based on the agency's own authority. That authority flows from a congressional delegation to promulgate substantive rules. . . ." 127 F.3d at 95. The court found that FDA's announcement:

> is not an interpretive rule. It does not purport to construe any language in a relevant statute or regulation; it does not interpret anything. Instead FDA's rule uses wording consistent only with the invocation of its general rulemaking authority to extend its regulatory reach.

Id. at 95.

Here, too, DEA's planned "interpretive" rule does not interpret anything. It is not possible to "interpret" THC as it currently appears on Schedule I to include hemp oil, cake and sterilized seed because THC as used in Schedule I does not include organic THC. What the "interpretive" rule would do is to regulate substances—hemp oil, cake and sterilized seed containing trace amounts of organic THC—that are currently unregulated. The "interpretive" rule, precisely because it is an exercise of regulatory authority under the CSA, is a substantive rule. Arguably, DEA may have authority to engage in such regulation under the CSA. But to do so, DEA must follow the formal rulemaking procedures mandated in the CSA and APA, and act within the bounds of the authority delegated in the underlying congressional enactment, the CSA. Cf. American Trucking Associations, Inc. v. Browner, 175 F.3d 1027 (D.C. Cir.), reh'g granted in part, 195 F.3d 4 (D.C. Cir. 1999), cert. granted, 120 S. Ct. 2003 (2000).

V. No "Good Cause" Exists for Issuing an Interim Rule Outlawing Production and Sale of Hemp Oil, Cake and Sterilized Seed Products

DEA has also announced its intent to issue an interim rule that would ban hemp products that result in any amount of THC entering the human body. Issuance of such an interim rule would suddenly, without notice or opportunity for comment, outlaw the production and sale of hemp oil, cake and sterilized seed products containing trace amounts of THC, including the products presently sold in the U.S. by the Hemp Seed and Oil Products Companies. Indeed, the issuance of such a rule would not only make such

production and sale a criminal violation but would render all existing stocks of these products illegal and potentially subject manufacturers, vendors, commercial carriers and retail purchasers of these products to harsh criminal penalties.

Interim rules may be issued under the authority of section 553(b) of the APA, which provides, in pertinent part, that:

> Except when notice or hearing is required by statute, this subsection does not apply—. . .
> (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

A. The "Good Cause" Exemption Is Inapplicable

In the case of a planned DEA interim rule, notice and hearing are indeed required by statute. The interim rule would have the effect of placing on Schedule I substances (hemp oil, cake and sterilized seed containing non-psychoactive trace amounts of organic THC), that are not currently on that Schedule, nor on any Schedule. The CSA and APA clearly require DEA to follow formal rulemaking procedures to add a new substance to any schedule of the CSA. 21 U.S.C. § 811(a). For that reason, under the APA, the "good cause" exception is inapplicable and DEA may not issue such a new scheduling as an "interim" rule.

B. There Is No "Good Cause" For Dispensing With Notice and Comment Rulemaking

Even if the statute itself did not require notice and hearing, there is no "good cause" for issuing an interim rule without any notice or opportunity for comment. The "good cause" exception to the APA's requirements for notice and comment rulemaking is to "be narrowly construed and only reluctantly countenanced." State of New Jersey Dept. of Environmental Protection v. EPA, 626 F.2d 1038, 1045 (D.C. Cir. 1980). See also, Zhang v. Slattery, 55 F.3d 732, 744-47 (2d Cir. 1995).

Here, in announcing its plans to issue an interim rule, DEA has made reference to the "need to protect the public health and safety." First, while an imminent public safety or health threat may constitute "good cause," use of the exception for these important reasons requires a true emergency situation. The "good cause" exceptions "are not 'escape clauses' that may be arbitrarily utilized at the agency's whim. . . . Rather, use of these exceptions by administrative agencies should be limited to emergency situations." American Federation of Government Employees v. Block, 655 F.2d 1153, 1156 (D.C. Cir. 1981)(emphasis added). "A true and supported or supportable finding of necessity or emergency must be made and published." State of New Jersey Dept. of Environmental Protection, supra, 626 F.2d at 1045, quoting S. Doc. No. 248, 79th Cong., 2d Sess. 200 (1946)(legislative history of APA). See also Thrift Depositors of America, Inc. v. Office of Thrift Supervision, 862 F. Supp. 586, 591 (D.D.C. 1994)(use of "good cause" exception "is limited to emergency situations"); Analysas Corp. v. Bowles, 827 F. Supp. 20, 24 (D.D.C. 1993)(SBA rule invalidated because the agency failed to conduct notice and comment rulemaking and did not show that "significant harm will befall the public" in the absence of the rule; interim rulemaking "emergency procedures are to be used only in rare cases").

Second, in the absence of a true emergency, the mere fact that public health and/or safety considerations are at stake does not justify dispensing with notice and comment procedures. In American Academy of Pediatrics v. Heckler, 561 F. Supp. 395 (D.D.C. 1983), HHS published an interim rule, without notice or opportunity for comment, requiring that hospitals receiving federal funding post notices warning that failure to provide customary food and medical care for severely defective newborn infants would violate federal law and authorizing immediate investigation and interventions by federal and state authorities. The agency argued that the need to save the lives of such infants justified issuance of an interim rule without notice or opportunity to comment under the "good cause" exception. The court disagreed:

> The Secretary [of HHS] argues that waiver [of APA requirements] is appropriate because "any delay would leave lives at risk." . . . Such an argument could as easily be used to justify immediate implementation of any sort of health or safety regulation, no matter how small the risk for the population at large or how long-

> standing the problem. There is no indication in this case of any dramatic change in circumstances that would constitute an emergency justifying shunting off public participation in the rulemaking.

561 F. Supp. at 401.

Finally, it is clear that, under these principles, DEA may not dispense with APA-mandated procedures, in the absence of a true broad public health or safety emergency, even when it believes that a new substance poses dangers, which have been overlooked and should be immediately regulated. In United States of America v. Gavrilovic, 551 F.2d 1099 (8th Cir. 1977), DEA had fully followed notice and comment procedures to place a new substance, mecloqualone, on Schedule I, but had made the scheduling immediately effective instead of providing 30 days notice before the regulation became effective. The Administrator invoked public health and safety in finding "good cause." The court rejected that finding and held that the immediate effective date was invalid:

> We think it clear that Congress intended to impose upon an administrative agency the burden of showing a public necessity for an early effective date and that an agency cannot arbitrarily find good cause. In determining whether the good cause exception is to be invoked, an administrative agency is required to balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable time to prepare for the effective date of its ruling. When the consequence of agency rule making is to make previously lawful conduct unlawful and to impose criminal sanctions, the balance of these competing policies imposes a heavy burden upon the agency to show public necessity.

551 F.2d at 1105 (emphasis added).

DEA had found, in the notice announcing the immediate effective date, that in enacting the CSA the Congress allowed DEA to consider the "potential" for abuse as well as actual abuse, thereby intending that DEA "should not be required to wait until a number of lives have been destroyed or substantial problems have already arisen before designating a drug as subject to the controls of" the CSA. 40 Fed. Reg. 28611 (July 8, 1975). The court, while acknowledging that potential for abuse could be considered, ruled that:

> [W]hether a drug has met the criteria for placement on the schedules of controlled substances is a separate question from whether a public necessity exists for an early effective date. This is not to say that general considerations of public health and safety cannot outweigh the public policy of giving adequate notice. . . The issue is whether the need is so great and the emergency so defined that it justifies administrative rule making without according the public the ordinary notice required by law.

Id (emphasis added).

In the case of hemp oil, cake and sterilized seed, there is no meaningful evidence of any threat whatsoever to public safety or health, let alone an imminent or substantial one amounting to a true emergency.

1. Hemp Oil, Cake and Sterilized Seed Products Pose No Threat to Public Safety

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 positive test results in workplace drug tests if federal guidelines for testing procedures are followed. As noted, the Hemp Seed and Oil Products Companies which manufacture products in the U.S. 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. Canadian regulations mandate less than 10 ppm in hemp oil, cake and sterilized seed, but the farmers and processors now consistently attain less than 5 ppm in the oil and less than 2 ppm in the seed, as do most European exporters.

The industry is aware of earlier studies, which indicated the possibility that ingestion of foods containing hemp seed or oil could cause false positives in drug testing. 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. Struempler, 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 food and cosmetic products now being sold in the U.S.

A study completed within the last year evaluated the effects on drug testing of consumption of hemp food products containing levels equivalent to those actually prevailing in products currently being sold in the U.S. G. Leson and P. Pless, "Evaluating Interference of THC in Hemp Food Products With Employee Drug Testing" (July 2000), study summary attached hereto as Exhibit 2 (full manuscript accepted for publication in Journal of Analytical Toxicology). The study found that even extended ingestion of up to 0.45 mg/day of THC as contained in a blend of hemp seed and canola oil did not result in positive tests at either the prevailing federal cutoff level of 50 parts per billion per immunoassay screen or at either the 10 ppb or 15 ppb THC confirmation cutoff by gas chromatography/mass spectrometry.

At the level of 2 ppm THC in hemp seeds, ingestion of 0.45 mg./day of THC would require eating 225 grams, or nearly half a pound, of hemp seeds—far more than is present even if ingesting vast quantities of the seeds or foods made from such seeds. At the level of 5 ppm THC in hemp oil, ingestion of 0.45 mg/day of THC would require consuming 95 mL/day, or almost half a cup, of straight oil—again, far more than is present even in great quantities of foods made with such oil, or would conceivably be taken as a dietary supplement for health reasons (recommended serving is 1 tablespoon = 15 mL).

Another current study confirms 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-tetrahydrocannibinol available in hemp seed products," 24 Journal of Analytical Toxicology 562 (2000). Hemp oils with THC levels ranging from 11.5 to 117.5 mg/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 use of cosmetics and body care products containing hemp oil is even less likely to cause false positives in drug testing. As the author of the July 2000 study, Gero Leson, communicated to you in a letter dated December 26, 2000, "This is due to the lower application rates of cosmetics, their low hemp seed oil content and the less efficient transdermal uptake of THC, compared to its ingestion." Dr. Leson observed, based on his own prior and ongoing research, that THC uptake rates from use of hemp cosmetics are less than 30 ug/day even under unrealistically conservative assumptions—much less than the conservative 450 ug/day required to cause false positives. Dr. Leson concluded, in that letter, that "even daily, extensive use of cosmetics containing hemp seed oil, which meets THC limits for food grade oil, will not cause positive screening tests, much less confirmed positives."

The recent research, while somewhat limited in scope, clearly indicates that there is no realistic possibility of widespread false positives in workplace drug testing from ingestion of food products made with the hemp seed or oil of the type used in the U.S., or from use of cosmetic and body care products made with hemp oil. For this reason, there is certainly no imminent, emergency threat to public safety of the type that would legally

justify issuing an interim rule banning the production and sale of such products in the U.S. [2]

2. Hemp Oil, Cake and Sterilized Seed Products Pose No Threat to Public Health

DEA did not, in its Unified Agenda announcement, identify any specific risk to public health from use of products made from hemp seed and/or hemp oil. The recent scientific research of which we are aware strongly indicates that there is no such risk, let alone a widespread or imminent one.

A recent study for the Nova Institute comprehensively reviewed the scientific literature on psychotropic and physiological effects of THC. F. Grotenhermen, M. Karus and D. Lohmeyer, "Hemp Foods and THC Levels: A Scientific Assessment," (1998) (attached hereto as Exhibit 3). The study concludes that:

> Available scientific evidence suggests that a single dose of 5 mg THC and a daily dose of 10 mg THC do not cause acute perceptible effects or chronic detrimental effects on health. Using a safety factor of 10, this leads to a pharmacologically innocuous daily THC intake of 1 mg for a healthy adult, corresponding to 0.014 mg of THC per kilogram of body weight.

Id. Part I at 1.

Based on average consumption of various types of food containing hemp seed, the authors find that no health effects at all would result from consumption of edible oil with a limit of 20mg/kg of THC. The authors conclude that, "Generally, the THC content of hemp food is so low that pharmacological or even psychotropic effects can be excluded with certainty, even if large quantities of food are consumed." Id. Preface at 4.

[2] Significantly, the drug testing issue has not become an issue in Canada or the European Union which share the United States' drug law enforcement concerns but which permit licensed cultivation, processing, distribution and exportation of industrial hemp seed and oil products.

Another recent study responded to a draft report entitled "Industrial Hemp Risk Assessment" issued by Health Canada: J. Geiwitz, "THC in Hemp Foods and Cosmetics: The Appropriate Risk Assessment" (2001)(attached hereto as Exhibit 4). This study agreed with the Nova Institute study that the no observed effects level for THC is .07mg/kg, about 5 mg for an average adult and, at the effect duration of 4 hours, 5 mg twice a day or 10 mg/day; with a safety factor of 10, resulting in "a tolerable daily dose of 14 ug/kg, about 1 mg THC for a 70 kg adult. This dose will have no psychoactive effects and no adverse health effects." Id. at 18. Based on this level, and taking into account average consumption of hemp foods, the study recommended that THC limits in hemp foods and cosmetics should be set at 20 ppm—higher than the level in foods permitted under existing Canadian regulations (10 ppm), and higher than levels in any of the products being sold in the U.S. by the Hemp Seed and Oil Products Companies. Indeed, as noted, the hemp oil and seed used by these companies is typically less than 5 ppm and 2 ppm THC respectively. Further, while sometimes sold by itself for ingestion or topical application, more often than not hemp oil or seed is incorporated as one of many ingredients into a finished formulation in which it (and its trace THC) is proportionally and often significantly diluted.

This research makes clear that there is no realistic threat to public health from use of hemp seed and oil in the food and cosmetics products being sold in the U.S. For many years, the DEA has been aware of the use of hemp seed foods and oils in the United States for human consumption. Indeed, the presence of THC residues in those hemp seed and oil products in years past, even at levels considerably higher than are now commonly present, had been documented in the scientific literature by 1997, as noted above. These products have been widely advertised and marketed. Manifestly, there is no imminent public health emergency posed by the use of hemp seed and oil for food and cosmetic purposes. For this reason, too, there is no legal justification for issuance of an interim rule banning production and sale of hemp seed and oil products in the U.S.

3. Scientific Controversy Itself Requires Notice and Comment Rulemaking

DEA may allege that no conclusive scientific evidence exists establishing the safety or health risks of hemp seed and oil. However, disagreement about the scientific evidence hardly justifies avoiding notice and comment rulemaking procedures. To the contrary, such disagreement makes it all the more necessary to follow such procedures.

For example, in Asbestos Information Ass'n v. OSHA, 727 F.2d 415 (5th Cir. 1984), OSHA had used its authority under its enabling statute to issue an emergency temporary standard, without notice or opportunity for comment, lowering workers' permissible exposure level to ambient asbestos fibers. OSHA justified its emergency regulation by citing the results of a risk assessment analysis. The Court of Appeals held that OSHA had not properly invoked its emergency powers and that the regulation was invalid:

> [W]e do not intimate at all that risk-assessment analysis is inappropriate evidence on which to base any standard, temporary or permanent. We say no more than that evidence based on risk-assessment analysis is precisely the type of data that may be more uncritically accepted after public scrutiny, through notice-and-comment rulemaking, especially when the conclusions it suggests are controversial or subject to different interpretations.

727 F.2d at 426 (emphasis added).

Here, too, if DEA has scientific evidence indicating—contrary to the studies cited above—a public safety or health risk posed by use of hemp seed or oil in the subject products, the appropriate response is to publish such evidence for public response and comment—not to avoid notice and comment rulemaking.

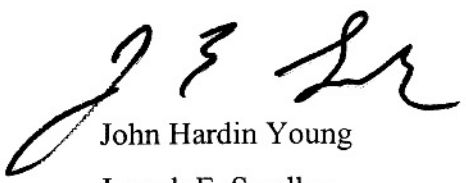
CONCLUSION

For the reasons stated above, DEA should not issue the planned interpretive or interim rules. Instead, if it wishes to attempt to schedule hemp seed or oil containing trace amounts of THC under the CSA, DEA must follow the formal rulemaking procedures mandated by the CSA and APA, thereby allowing for full consideration and analysis of all of the relevant evidence and factors.

Representatives of the Hemp Seed and Oil Products Companies would be pleased to meet with DEA officials to discuss further the issues raised above and the development of an appropriate rulemaking procedure, if that would prove useful. In the meantime, if you have any questions or need further information concerning the above, please contact the undersigned.

Thank you for your time and attention to this important matter.

Sincerely yours,



John Hardin Young

Joseph E. Sandler