UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. _____

Hemp Industries Association;	)
All-One-God-Faith, Inc. d/b/a/ Dr. Bronner's Magic	)
Soaps; Atlas Corp.; Nature's Path Foods USA, Inc.;	)
Hemp Oil Canada, Inc; Hempzels, Inc.; Kenex Ltd.;	)
Tierra Madre, LLC; Ruth's Hemp Foods, Inc.;	)
Organic Consumers Association,	)
	)
Petitioners	)
	)
v.	)
	)
Drug Enforcement Administration;	)
John B. Brown III, as Acting Administrator,	)
Drug Enforcement Administration,	)
	)
Respondents	)
	)

URGENT MOTION OF PETITIONERS
FOR STAY PENDING REVIEW

Pursuant to Rules 18 and 27 of the Federal Rules of Appellate Procedure, and Ninth Circuit Rule 27-3(b), Petitioners hereby urgently move the Court for an order staying the "Final Rule—Clarification of Listing of 'Tetrahydrocannabinols' in Schedule I" issued by Respondent Drug Enforcement Administration ("DEA") on March 18, 2003, 68 *Fed. Reg*. 14114 (March 21, 2003)(the "Final Clarification Rule"), pending this Court's review of that rule, insofar as the Final Clarification Rules purports to make unlawful the importation, manufacture, distribution or sale

of hemp seed or hemp seed oil, or edible products derived therefrom. A Petition for Review has been filed today pursuant to Rule 15(a), Federal Rules of Appellate Procedure. A copy of the Final Clarification Rule is attached hereto as Ex. 1.

I. PROCEDURAL BACKGROUND

Petitioners are companies that manufacture, distribute and/or sell, in the US, processed hemp seed or oil, or food products containing hemp seed or oil, or which use hemp oil in the U.S. manufacture of products such as personal care items (soap, shampoos, lotions, etc.).[1] Such seed, oil or products may contain non-psychoactive miniscule trace amounts of residual resin which contains naturally occurring tetrahydrocannabinols ("THC"). Hemp seed and oil, and products made from such seed and oil, have never been treated as controlled substances under the Controlled Substances Act, 21 U.S.C. §§802 et seq. ("CSA"). Petitioners have been lawfully importing and distributing seed and oil, and/or manufacturing and selling food and cosmetic products made from such seed and oil, for many years.

On October 9, 2001, with no opportunity for notice and comment, DEA published an "Interpretive Rule" purporting to "interpret" the CSA 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 (Oct. 9, 2001)(emphasis added). This "Interpretive Rule," made effective immediately

[1] Petitioner Hemp Industries Association ("HIA") is a trade association representing more than 250 hemp food, clothing and bodycare companies and retailers of such products. The 2002/2003 Vote Hemp Report is attached to the Declaration of David Bronner, Ex. 3,which provides a concise overview of the hemp industry HIA represents.

upon publication, would have had the effect of instantly transforming Petitioners' long-standing business activities into a criminal offense. Simultaneous with its publication of the "Interpretive Rule," DEA published a "Proposed Rule and Request for Comments," 66 *Fed. Reg*. 51535 (Oct. 9, 2001)("Proposed Rule"). 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." Thus, DEA initiated a notice and comment rulemaking on a "proposed" rule identical to its "Interpretive Rule." DEA also published, on the same date, an "Interim Rule" exempting from the "Interpretive Rule" products that are not used, or intended for use, for human consumption, and providing a "grace period," until February 6, 2002, for any person or company possessing a THC-containing hemp product to dispose of such product. 66 *Fed. Reg*. 51539, 51543 (Oct. 9, 2001).

On October 19, 2001, HIA, certain of the Petitioners herein and other companies filed a Petition for Review of the "Interpretive Rule" and an Urgent Motion for Stay Pending Review of the "Interpretive Rule." *Hemp Industries Ass'n v. Drug Enforcement Administration*, No. 01-71662 (9th Cir., filed Oct. 19, 2001). On February 6, 2002, with the "grace period" under the "Interpretive Rule" about to expire, petitioners in No. 01-71662 filed an Emergency Motion for Stay. After the Court inquired of DEA whether DEA intended to enforce the interpretive rule prior to the Court's ruling on the Emergency Motion, DEA's counsel notified the Court that DEA would extend the grace period for an additional 40 days, to

allow the Court time to rule on the Emergency Motion prior to the expiration of the grace period. On March 7, 2002, the Court issued an Order granting the Emergency Motion for Stay pending review, "through the date of hearing of the appeal on the merits and until further order of the Court." Order, No. 01-71662 (9th Cir., filed March 7, 2002). Case No. 01-71662 has now been briefed, argued (on April 8, 2002) and submitted, on the merits; no decision has yet been issued.

In the meanwhile, DEA proceeded with its rulemaking under the October 2001 Proposed Rule (identical to the "Interpretive Rule"), affording opportunity for public comment. Petitioner HIA and a number of its member companies timely submitted comments on the Proposed Rule. On March 21, 2003, DEA published the Final Clarification Rule, amending its regulations, 21 C.F.R. §1308.11(d)(27), to add "naturally contained" THC to its regulatory definition of THC, with the sole effect of adding to Schedule I of the CSA hemp stalk, seed and oil which may contain any amount whatsoever of non-psychoactive miniscule trace amounts of residual resin which contains naturally occurring THC. DEA did not hold any hearing on this rule, nor did it make any of the findings required to add these substances to the CSA Schedules, under 21 U.S.C. §811(a).

At the same time, DEA issued a "Final Rule—Exemption from Control of Certain Industrial Products and Materials Derived from the Cannabis Plant," 68 *Fed. Reg*. 14119 (March 21, 2003)("Final Exemption Rule," attached hereto as Ex. 2), making final its earlier "Interim Rule"—that is, exempting from control trace

THC-containing hemp fiber, seed and oil products as long as they are not intended for human consumption. Because Petitioners' food products are used, or intended to be used, for human consumption, Petitioners' products are not covered by this exemption. Further, although personal care products made with hemp oil may be exempted under some circumstances (*id*. at 14121-22), the hemp oil imported for use in the U.S. for manufacture of such products has not been exempted. Thus, the importation, U.S. manufacture and/or sale in the U.S. of Petitioners' hemp seed and oil products has been rendered unlawful by the Final Clarification Rule, which will become effective by its terms 30 days after publication, on April 21, 2003.

II. JURISDICTION

This Court has jurisdiction of the Petition for Review and this Urgent Motion for Stay under section 507 of the CSA, 21 U.S.C. §877, that states:

> All final determinations, findings and conclusions of the Attorney General under this title shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days….

The Final Clarification Rule is a "final determination" of DEA within the meaning of section 877. Petitioners HIA, All-One-God-Faith, Inc. and Atlas Corp. all have their principal places of business in California, within this Circuit.

III. NO INTERIM RELIEF IS AVAILABLE FROM THE AGENCY

There is no procedure in the CSA or in the DEA's regulations for requesting a stay of a scheduling determination or of an amendment to DEA's regulations, pending Court review of such action. FRAP 18(a)(2)(ii). To the extent DEA could have granted the relief requested here, i.e., not issuing the Final Clarification Rule, all grounds advanced in support of such relief in this Motion were submitted to the agency in HIA's comments on the Proposed Rule. Ninth Circuit Rule 27(3)(b)(4).

IV. FACTUAL BACKGROUND

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.[2] Regulations in the EU and Canada conservatively mandate less than 0.2 and 0.3% of THC in industrial hemp flowers, respectively. By contrast, marijuana varieties typically contain 3 to 15% THC in their flowers. Due to minimal THC content, flowers from industrial hemp have *no* potential for drug use.

For seed, hemp is harvested when the seed is mature and ready for combining. See U.S. Dept. of Agriculture, "Industrial Hemp in the United States: Status and Market Potential" 7, 10 (Jan. 2000)("USDA Study"). Most of the seed's value is derived from either dehulling the whole seed and/or crushing it for oil. Hemp seeds supply essential amino acids in an easily digestible form with a high protein efficiency ratio; the hemp oil offers a high concentration of the two

[2] This distinction is formally affirmed in Article 28(2) of the United Nations' Single Convention on Narcotic Drugs, 1961, to which the United States is a signatory party: "This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes."

essential fatty acids in an optimum ratio of the omega 3/omega 6 acids. Because of this nutritional profile, hemp nut and oil are increasingly used in natural food products such as corn chips, nutrition bars, nondairy milks, breads and cereals.

The hemp seed (or nut) itself contains only miniscule 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 trace resin residue on the outer shells. 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*.[3]

[3] DEA's suggestion that it lacks authority to establish an "acceptable" level of THC in foods, Final Exemption Rule, Ex. 2, 68 *Fed. Reg*. at 14124, is inapposite. No one is "adding" THC to foods, just as no one is "adding" morphine to bagels. DEA's suggestion that the presence of infinitesimal trace amounts of THC naturally occurring in hemp seed is comparable to allowing manufacturers to deliberately add some small non-drug amount of heroin or LSD in food, *id*., is baseless. Heroin and LSD are synthesized drugs that are intentionally manufactured for drug purposes, and obviously no amount of such substances can be declared legal to be manufactured for the addition to food. The naturally occurring trace opiates in poppy seeds, the naturally occurring trace alcohol in fruit juices, or the naturally occurring trace THC in hemp seed and oil, are an entirely different matter. Without any manufacture, concentration or synthesis of any kind, the amount present in these edible products remains miniscule and harmless. There is no question here of whether DEA should "allow" drugs in food products by permitting the sale of poppy seeds on rolls and bagels or hemp seed and oil in waffles, nutrition bars, etc. The Canadian government has set a 10 ppm tolerance in hemp seed and oil for naturally occurring trace THC to address public health and safety, just as the FDA has done for alcohol and innumerable other substances in foods. In fact, the hemp seed and oil in petitioners' companies generally contain undetectable THC in the seed and oil they use according to the official Health Canada detection protocol which has a 4 ppm limit of detection. THC, unlike pesticides and heavy metals allowed at non-zero tolerances in the U.S. food supply, is not characterized by a high acute toxicity and is not a known or probable carcinogen, and as DEA notes, synthetic THC in pill form is an FDA approved Schedule III medicine that is prescribed everyday to address nausea and stimulate appetite. DEA notes that FDA declined to affirm GRAS (Generally Recognized As Safe) status for hemp foods based on the historical widespread use criteria. Particularly in the "natural foods" sector, this is not unusual and does not imply that a food is not safe for human consumption. For instance, flax oil was sold in the U.S. market for years before obtaining FDA affirmed GRAS status in 1998. The hemp industry plans to petition the FDA to affirm GRAS status for hemp seed based on scientific evidence on the safety and nutritional value of these products.

The companies currently selling hemp seed and oil food, nutritional and personal care 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. Attached as Exhibits 3 through 10 hereto are Declarations from the chief executive officers of each Petitioner company explaining the nature of its business.

V. GROUNDS FOR RELIEF

In this Circuit, the "standard for evaluating stays pending appeal is similar to that employed by district courts in deciding whether to grant a preliminary injunction." *Lopez v. Heckler*, 713 F.2d 1432, 1435 (9th Cir.), *rev'd in part on other grounds*, 463 U.S. 1328 (1983). "Petitioner must show either a probability of success on the merits and the possibility of irreparable injury, or that serious legal questions are raised and the balance of hardships tips sharply in petitioner's favor." *Abbassi v. Immigration and Naturalization Service*, 143 F.3d 513, 514 (9th Cir. 1998). In this case, Petitioners are highly likely to succeed on the merits; they will suffer irreparable injury in the absence of a stay; and the balance of hardships is sharply in favor of Petitioners.

A. Petitioners Are Likely to Succeed on the Merits

The issue on the merits presented by the Petition for Review, as to the Final Clarification Rule, is whether DEA's "clarification" is actually, with respect specifically to hemp stalk, seed and oil, legally a rescheduling action under and

subject to 21 U.S.C. §811. If so, the Final Clarification Rule is clearly invalid, as it is undisputed that DEA failed to comply with the requirements of section 811.

1. Petitioners' Products Were Not Controlled Substances Prior to Issuance of the Final Clarification Rule

The hemp seed and oil, and products made from such seed and oil, which Petitioners import, manufacture, distribute and/or consume, were not controlled substances under the CSA prior to issuance of the Final Clarification Rule.[4]

The basic reason is that the CSA exempts hemp stalk, seed and oil from the definition of "Marihuana", notwithstanding that such stalk, seed and oil may contain non-psychoactive miniscule trace amounts of residual resin with naturally-occurring trace amounts of THC. DEA's position, as set forth in the Final Clarification Rule, is that, having expressly excluded hemp stalk, seed and oil from the definition of "Marihuana," Congress nevertheless intended to include them in the definition of "THC" if they contain any amount whatsoever of THC. This position is contrary to the plain language of the statute and makes no sense.

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

[4] The "Interpretive Rule" would have made hemp seed and oil controlled substances but the "Interpretive Rule" never actually became effective, due to this Court's action granting the Emergency Motion for Stay in No. 01-71662.

> 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 stalk, oil, cake and sterilized seed are *not* controlled as "Marihuana" under Schedule I of the CSA. In fact, the express exclusion of hemp stalk, 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.*, 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 (April 1937). Petitioners who have been making products with hemp oil or seed have reasonably relied on the express exclusion of these products created by Congress when the legal definition of "Marihuana" was adopted in 1937 and reaffirmed in the CSA.

DEA argues, in the Final Clarification Rule, that the statutory listing of "Tetrahydrocannabinols" in Schedule I was made without distinction between naturally occurring and synthetic THC, and that hemp stalk, seed and oil—despite the express statutory exclusion—can therefore simply be regulated as THC if they contain any THC whatsoever. Ex. 1, 68 *Fed. Reg*. at 14114-15. Indeed, DEA contends that its rule actually "does not change the legal status of so-called 'hemp' products", *id*. at 14114, because:

> For the reasons provided in the interpretive rule, it is DEA's view that the CSA and DEA regulations have always (since their enactment more than 30 years ago) declared any product that contains any amount of tetrahydrocannibols to be a schedule I controlled substance. This interpretation holds regardless of whether the product in question is made from 'hemp'….

Id. at 14115.

In fact, although DEA contends that the "plain language" of the CSA includes both natural and synthetic THC under the listing of THC, the term "THC", as used in CSA Schedule I, covers only "any material, compound, mixture or preparation, which contains any quantity of" THC (emphasis added), words that clearly connote only *synthetic* or manufactured substances, not parts of a plant. This plain statutory language thus does not refer to the trace organic, naturally-occurring THC found in hemp stalk, 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), where the Court 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. This Circuit is in accord as demonstrated by the Court's decision in *United States v. Wuco*, 535 F.2d 1200 (9th Cir.), *cert. denied*, 429 U.S. 978 (1976), in which the U.S. Department of Justice conceded that the listing of "Tetrahydrocannabinols" in Schedule I is limited to synthetic THC; this Court agreed that "organic THC . . . is not the synthetic THC defined as a Schedule I controlled substance." *Id*. at 1202.

But even if DEA could somehow interpret the statutory language defining THC—contrary to its plain meaning--to include naturally-occurring THC, that language could not possibly be read to authorize DEA to regulate hemp stalk, seed and oil as THC merely because such substances may contain naturally occurring trace amounts of THC. Congress was clearly aware that the resin of hemp stalk, seed and oil might contain trace amounts of THC because Congress took pains to include the resin itself as a controlled substance—that is, the exemption for stalks, fiber, oil, cake and sterilized seed itself exempts—and thus brings back under control—the "resin extracted therefrom." 21 U.S.C. §802(16). Congress knew and understood that the stalk, seed and oil might contain some THC-containing resin—based on the plain language of the definition. Congress nevertheless

exempted hemp stalk, seed and oil from the definition of "Marihuana" while prohibiting the extraction and concentration of resin from such stalk, seed and oil.[5]

The introductory language to the relevant part of CSA Schedule I provides that any material containing any of the listed substances, including THC, is covered, "*Unless specifically excepted*…" (emphasis added). And hemp stalk, seed and oil *are* "specifically excepted" right in Schedule I of the CSA.[6]

"[I]n expounding a statute we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *Prince v. Jacoby*, 303 F.3d 1074, 1082 (9th Cir. 2002), *quoting* U.S. *Nat'l Bank of Oregon v. Independent Ins. Agents of America, Inc*. 508 U.S. 439, 455 (1993). In this case, why would Congress bother to exempt hemp stalk, oil and seed from one part of Schedule I only to provide that another part of Schedule I covers hemp stalk, oil and seed?

Further, a court must be "hesitant to adopt an interpretation of a congressional enactment which renders superfluous another portion of that same law." *Kawaaihau v. Geiger*, 523 U.S. 57, 62 (1998), *quoting Mackey v. Lanier*

[5] Indeed, Susan Miller, a forensic scientist employed by DEA, clarified in an Affidavit on April 11, 1991, that despite the "determination of the presence of THC" in seeds, "the law specifically states that sterilized seeds incapable of germination are not included in the term 'Marihuana' and are therefore not controlled."

[6] Contrary to DEA's contention (Ex. 1, 68 *Fed. Reg*. at 14116), the CSA treats poppy seed and hemp seed in exactly the same way. Both opium poppy and opiates are Schedule II controlled substances (21 U.S.C. §812, Schedule II(a)(1) & (3). The CSA defines "opium poppy" to include all parts of the poppy plant except the seeds. 21 U.S.C. §802(19). That trace amounts of separately controlled opiates—in the residual opium resin—are present on poppy seeds does not bring under control the poppy seeds that Congress has specifically exempted—just as the trace amounts of THC, a separately controlled substance, present in the residual resin of hemp seed does not bring those seeds under control given that Congress has specifically exempted them. (See Statutory Appendix hereto).

Collection Agency & Service, Inc., 486 U.S. 825, 837 (1988). If DEA can merely interpret the CSA reference to "THC" to include hemp stalk, seed and oil, then the statutory exemption for hemp stalk, seed and oil would be rendered superfluous.

That hemp stalk, oil, and sterilized seed were not controlled by the CSA prior to DEA's "clarification" has been confirmed by the Criminal Division of the U.S. Department of Justice, of which DEA, of course, is a part. In letters to both the US Customs Commissioner and DEA Administrator dated March 22 and 23, 2000, attached hereto as Ex. 12, 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 stalk, oil 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. . . . Congress has made its intent known by specifically excluding these products from its definition of marijuana*.

(emphasis added).

The clear intent of Congress was to exempt hemp stalk, seed and oil from the CSA. An agency "cannot contravene the will of Congress through its reading

of administrative regulations." *League of Wilderness Defenders v. Forsgren,* 309 F.3d 1181, 1185-86 (9th Cir. 2002). "If the intent of Congress is clear, 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." *Id*. at 1186, *quoting Chevron , U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 842-43 (1984).

2. The Final Clarification Rule Is A Scheduling Action

DEA claims that its final rule is not a rescheduling action because it "does not change the schedule of THC or any other controlled substance. To the contrary, when this final rule becomes effective, …THC will remain in the same schedule in which it has been." Ex. 1, 68 *Fed. Reg*. at 14116.

The issue, however, is not whether THC is being scheduled, or rescheduled, but whether *hemp stalk, seed and oil* are being scheduled. Because hemp stalk, seed and oil are not currently covered by any schedule of the CSA, DEA's Final Clarification Rule constitutes a scheduling action—that is, putting new substances on Schedule I of the CSA.[7]

[7] DEA claims that, absent the Final Clarification Rule, it would be legal to import into the U.S. "unlimited quantities of cannabis stalks and sterilized seeds," which anyone could use to produce "a highly potent extract" of THC "that would be considered a noncontrolled substance." Ex. 1, 68 *Fed. Reg*. at 14114. Aside from the fact that such a hypothetical has never happened in the US and is technically and economically prohibitive, it is also simply untrue: such an extract would necessarily be derived from the resin of the seeds and stalks, which is already controlled under the CSA as "Marihuana" as a derivative of the resin. The same would be true of the psychoactive Swiss salad oil referred to in the Final Exemption Rule, Ex. 2, 68 *Fed. Reg*. at 14123, produced by pressing excessive quantities of marijuana-grade resin with marijuana seeds—such a substance would itself be controlled as "Marihuana". Indeed, there is no current or potential class of substances capable of abuse that is not already controlled as either "Marihuana" or synthetic "THC" in the CSA. DEA would not maintain that there is an unaddressed loophole in the CSA such that narcotic quantities of opium resin are legal if present in otherwise exempt poppy seed or oil products.

3. CSA Requirements for Rescheduling

Without question, DEA has the authority to place new substances on a CSA Schedule—be they grapefruit juice, peanut butter or thumbtacks, but only if certain criteria are met. 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 to 21 U.S.C.§812(b), however, 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).

Thus, "[t]o add a substance to a schedule under the 'permanent' scheduling authority, the Attorney General must find the substance has a 'potential for abuse' and make the requisite findings of section 812." *United States v. Emerson*, 846 F.2d 541, 543 (9th Cir. 1988).

Further, section 811(a) 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 Administrative Procedure Act ("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). Thus, "any scheduling by the Attorney General must be made in accordance with the formal rule-making requirements of the Administrative Procedure Act." *U.S. v. Emerson*, *supr*a, 846 F.2d at 543.

Nowhere in its Final Clarification Rule does DEA make any of the findings required by section 811(a) for hemp stalk, seed and oil. Because the Final Clarification Rule was thus adopted in violation of the CSA's clear requirements, the rule is manifestly invalid. For this reason, Petitioners are likely to prevail on the merits of their Petition for Review.

B. Petitioners Will Suffer Irreparable Injury

It is clear that, in the absence of a stay of the Final Clarification Rule, the individual Petitioner companies will suffer irreparable injury, because their business activities have been instantly rendered unlawful.[8] Indeed, DEA makes clear in the rule that "once this rule becomes final, …and a federal prosecution were commenced, the court would be required to apply the new regulation." Ex. 1, 68 *Fed. Reg*. at 14115.[9]

[8] DEA's suggestion (68 Fed. Reg. at 14118) that the rule may have limited effect because one hemp food company claims its products contain no THC without qualification, is baseless. That claim has been found to be inaccurate—the company's products do contain trace amounts of THC—and for that reason along with slanderous attacks on other companies, HempNut was removed from the HIA in March 2002.

[9] Under the Federal Sentencing Guidelines, §§2D1.1:1 et seq. & 2D1.1:13: one, the "carrier," i.e. the food product containing an infinitesimal trace THC is counted in determining the amount of the drug in question; and two, once the "amount" is determined (i.e. the total weight of the hemp snack bars, bags of chips, etc. in question), the conversion formula is 167 times the equivalent amount of marijuana. Thus, a manufacturer with a pallet of 100 cases of hemp seed corn chips (twenty 8 oz. bags per case) in their warehouse, would have 1,000 lbs. of "THC" according to the DEA, which equals 167,000 lbs. of "marijuana" (or about 76,000 kilos) for sentencing purposes.

Thus, Petitioner companies must shut down their operations relating to importation, manufacture and sale of processed hemp seed and oil, and oil and seed food, nutritional, beverage and personal care products, or face the risk of criminal prosecution. *See, e.g.,* Bronner Dec., Ex. 3 hereto, at ¶9 (rule "threatens to immediately shut down our entire business" involving hemp nut nutrition bar and "destroy a significant portion of" sales of soap products made with hemp oil); Declaration of Arran Stephens, Ex. 5 hereto at ¶8 (rule "threatens to immediately shut down our best-selling HEMP PLUS Granola and HEMP PLUS Waffles lines, causing employee lay-offs, loss of substantial sales…."); Declaration of Ruth Shamai, Ex. 10 hereto at ¶9 (rule "threatens to immediately shut down our US export business involving the sale and distribution of our hemp food products into the USA…perhaps forcing us to go out of business"). *See* to the same effect Declaration of Erik Rothenberg, Ex. 4 hereto at ¶¶ 8-9; Declaration of Shaun Crew, Ex. 6 hereto at ¶ 8. If the Final Clarification Rule were ultimately ruled invalid, such a ruling would come too late to save these companies' business operations.

C. The Balance of Hardships Favors Petitioners

In this case, the "balance of hardships tips sharply in petitioner's favor." *Abbassi*, 143 F.3d at 514. On the one hand, in the absence of a stay, the individual Petitioner companies will be forced to shut down their business operations relating to the manufacture and sale of hemp seed and oil, and seed and oil products, or face the prospect of criminal prosecution and long jail terms; some companies may

well be forced out of business altogether, as the attached Declarations show. *See* section IV(B), *supra*. In addition, consumers and businesses throughout the nation will be affected as these hemp products are distributed in virtually every city and town in the U.S. *See* Declaration of Ronnie Cummins (Organic Consumers Association), Ex. 11 hereto.

On the other hand, it is clear that DEA will suffer no hardship from a stay. DEA promulgated its Proposed Rule on October 9, 2001 and did not issue its Final Rule until March 21, 2003—nearly 18 months later. Obviously, having waited over a year to issue these rules, DEA does not believe the products in question pose any threat to public health or safety, let alone an imminent threat warranting immediate placement of these products in Schedule I.

Further, as discussed in note 7 *supra*, DEA's suggestion that its rule is needed to prevent the extraction of THC from the resin of hemp stalk, seed or oil, Ex. 1, 68 *Fed. Reg*. at 14114, is utterly baseless, whether such resin extract is in salad oil or existing as pure refined THC, because any such substance derived from resin would *already* be covered by the CSA as "Marihuana", as a derivative of the resin. The sole intent and effect of DEA's rules is the scheduling of the Congressionally exempted non-drug substances hemp stalk, seed and oil that contain trace insignificant amounts of resin. There is no threat of any kind to public health or safety posed by continuing to allow the long-lawful importation

and use of hemp oil and seed, and manufacture of edible hemp seed and oil products, pending review of the Final Clarification Rule by this Court.

For these reasons, the balance of hardships sharply favors the Petitioners.

CONCLUSION

For the reasons set forth above, the Court should grant a stay of DEA's Final Clarification Rule pending this Court's review of that rule.

Respectfully submitted,

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Dated: March 28, 2003