UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. _____

Hemp Industries Association; Nutiva, Inc.; Tierra Madre, LLC; Hemp Oil Canada, Inc; North Farm Cooperative; Kenex Ltd.; Nature's Path Foods USA, Inc.; and Hempola, Inc.	)
Petitioners	)
v.	)
Drug Enforcement Administration; Asa Hutchinson, as 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 "Interpretive Rule" issued by Respondent Drug Enforcement Administration ("DEA") on October 2, 2001, 66 Fed. Reg. 51530 (Oct. 9, 2001), pending this Court's review of the "Interpretive Rule." A Petition for Review has been filed today pursuant to

Rule 15(a), Federal Rules of Appellate Procedure. A copy of the "Interpretive Rule" is attached hereto as Exhibit 1.

As explained in detail below, Petitioners are companies that manufacture, distribute and/or sell, in the United States, processed hemp seed or oil, or food and beverage products containing processed hemp seed or oil, which seed, oil or products may contain non-psychoactive miniscule trace amounts of residual resin which contains naturally occurring tetrahydrocannibinols ("THC").[1] 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 beverage 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. at 51533 (emphasis added). This "Interpretive Rule," made effective immediately upon publication, has 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), attached hereto as Exhibit 2. 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 has initiated a notice and comment rulemaking on a "proposed" rule

[1] Petitioner Hemp Industries Association is a trade association representing more than 250 hemp oil, hemp seed and hemp fiber, hemp food, clothing, beverage and bodycare companies and retailers of such products.

which is identical to a rule that it has put into effect immediately—without any notice or comment—through the "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. 66 Fed. Reg. 51539 (Oct. 9, 2001), attached hereto as Exhibit 3. Because Petitioners' food and beverage products are used, or intended to be used, for human consumption, Petitioners' products are not covered by this exemption; thus, the importation, manufacture and sale of such products has been rendered unlawful by the "Interpretive Rule." Further, although the "Interim Rule" purports to provide a 120-day "grace period" for companies which possess hemp seed and oil products containing trace THC and intended for human consumption to "dispose" of such products, the "Interim Rule" makes clear that it is immediately unlawful for any person to "manufacture or distribute such a product with the intent that it be used for human consumption within the United States." Id. at 51543. Thus, the manufacture and distribution by Petitioners of their various products is illegal right now.

The grounds for issuing a stay pending review are compelling. First, Petitioners are likely to prevail on the merits because it is clear that DEA's so-called "Interpretive Rule" is a final, substantive, legislative rule-- rendering criminal one day conduct that was lawful the day before—issued without notice or opportunity to comment as required by the Administrative Procedure Act, let alone formal rulemaking on the record after opportunity for hearing as required by the CSA, 21 U.S.C. §811(a), for listing new substances on Schedule I. Second, Petitioners will be irreparably harmed unless a stay is granted, because they will be forced to cease business operations or risk facing criminal

charges, pending a decision on the merits of the Petition for Review. Third, the balance of hardships clearly favors Petitioners: the "Interpretive Rule" will force Petitioners to cease substantial parts, or in some cases all, of their business operations, while DEA has not claimed that any delay in implementing its new rule would pose any threat to public health or safety. Indeed, DEA has for almost a year announced its intention to adopt rules of this nature, without taking action until last week.

I. 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, which provides that:

> 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 after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

As demonstrated below, the "Interpretive Rule" is clearly a final decision of DEA. Petitioners Hemp Industries Association and Nutiva, Inc. have their principal places of business in California, within this Circuit. See Declaration of John Roulac, Nutiva, Inc. ("Roulac Dec."), attached hereto as Exhibit 4.

II. NO INTERIM RELIEF IS AVAILABLE FROM THE AGENCY

Almost a year ago, DEA announced its plans to publish the three rules—the "Interpretive Rule," the "Proposed Rule" and the "Interim Rule"—in the Department of Justice Annual Regulatory Agenda. 65 Fed. Reg. 74004, 74025 (Nov. 30, 2000). DEA

did not institute any rulemaking proceedings at that time, or invite any comments. Nevertheless, on February 16, 2001, several of the Petitioners, together with a number of other companies, submitted to DEA a detailed presentation as to why the "Interpretive Rule" would violate the Administrative Procedure Act and the CSA. That presentation included all of the grounds set forth in this Motion and specifically requested that the "Interpretive Rule" not be issued.

DEA never responded to that submission and, indeed, never even acknowledged receiving it.

There is no procedure in the CSA or in the DEA's regulations for requesting a stay of an interpretive rule, pending Court review of such action.

Accordingly, the relief requested here has in fact been requested from the agency, FRAP 18(a)(2)(ii). To the extent DEA could have granted the relief requested here—i.e., not issuing the "Interpretive Rule"—all grounds advanced in support of such relief in this Motion were submitted to the agency. Ninth Circuit Rule 27(3)(b)(4).

III. 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. 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. See U.S. Dept. of Agriculture, "Industrial Hemp in the United States: Status and Market Potential" 7, 10 (Jan. 2000)("USDA Study"). For many years, U.S. individuals and businesses have legally purchased, used, and traded in sterilized and non-psychoactive 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.

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. 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 essential fatty acids in an optimum ratio of the omega 3/omega 6 acids. (Kentucky Study at 7-8). Because of this nutritional profile, shelled hemp seed and oil are increasingly used in natural food products such as corn chips, nutrition bars, hummus, nondairy milks, breads and cereals.

The companies currently selling hemp seed and oil food, beverage and nutritional products in the U.S. generally either import hemp seed and oil from Canada or Europe for use in manufacturing products in the U.S., or import already finished products from Canada or Europe. Petitioner Nutiva manufactures, and sells throughout the U.S, hemp food products, including bars, chips and cans of shelled hempseeds, all using shelled hemp seeds. Roulac Dec., Exhibit 4 hereto at ¶¶ 3-4. Petitioner Tierra Madre has developed a non-dairy hemp beverage, manufactured from processed hemp seed, which beverage the company is about to distribute throughout the U.S. Declaration of Joseph W. Hickey, Sr. ("Hickey Dec."), Exhibit 5 hereto. Petitioner Hemp Oil Canada manufactures in Canada, and sells in the U.S., hemp oil and seed products including hemp seed oil, gelcaps, hulled hemp seed, toasted hemp seed, hemp flour and hemp

coffee. Declaration of Shaun Crew ("Crew Dec."), Exhibit 6 hereto at ¶¶ 3-4. Petitioner North Farm Cooperative distributes food products made from hemp seed including breads, bars, waffles and granola. Declaration of Mark Slagh ("Slagh Dec."), attached as Exhibit 7 hereto at ¶¶3-4. Petitioner Hempola manufactures in Canada, and sells throughout North America, hemp seed oil, supplements, salad dressings and hemp flour, pancake mix and pasta. Declaration of Greg Herriott ("Heriott Dec."), attached as Exhibit 8 hereto at ¶¶ 3-4. Petitioner Kenex grows and processes industrial hemp in Canada and exports to the U.S. hemp seed oil and hulled hemp seed, and hemp seed and oil products. Declaration of Jean-Marie Laprise ("Laprise Dec."), attached as Exhibit 9 hereto at ¶ 3. Petitioner Nature's Path Foods produces and sells in the U.S. hemp cereals and produces in Canada, and sells in the U.S., toaster waffles containing hulled hemp seed. Declaration of Arran Stephens ("Stephens Dec."), attached as Exhibit 10 hereto at ¶¶1, 4.

IV. 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). These standards "represent the outer extremes of a continuum, with the relative hardships to the parties providing the

critical element in determining at what point on the continuum a stay pending review is justified." Id.

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 is not whether DEA has made a permissible interpretation of the CSA or of DEA's own regulations. Rather, the issue is whether DEA's "interpretation" is legally a final, substantive legislative rule which DEA has issued without notice and comment as required by the Administrative Procedure Act ("APA"), 5 U.S.C.§553, and without formal rulemaking on the record after opportunity for hearing as required by the CSA. It is manifest that, in issuing its "Interpretive Rule," DEA has violated the APA and CSA because the "Interpretive Rule" affects substantive rights, was made pursuant to legislative power delegated by Congress and effectively revokes the current legislative regulation having the force of law.

1. Petitioners' Products Were Not Controlled Substances Prior to the "Interpretive Rule"

The processed hemp seed and oil, and products made from such seed and oil, which Petitioners import and/or manufacture, distribute and sell, were not controlled substances under the CSA prior to issuance of the "Interpretive Rule." To the contrary, the law prior to the "Interpretive Rule" clearly excluded Petitioners' products, and that fact was recognized and adopted by the U.S. Department of Justice itself, of which DEA is a part. The prior Department of Justice position was that these products are outside the prohibitions of the CSA. The reason is that the CSA treats the naturally-occurring trace

amounts of THC in Petitioners' products neither as "Marijuana" nor as "THC" for purposes of the CSA.

Non-psychoactive 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), in full compliance with Article 28(2) of the United Nations' Single Convention on Narcotic Drugs, 1961, to which the U.S. is a signatory party. ("This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes"). 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. 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.

The CSA controls two materials relevant here: the Cannabis sativa plant itself, and synthetic THC. CSA Schedule I (c)(10), 21 U.S.C. §812(c) covers "Marihuana," which is defined to include "all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or

resin." 21 U.S.C. §802(16). The Cannabis sativa plant itself is covered in Schedule I regardless of its THC content. New Hampshire Hemp Council, Inc. v. Marshall, 203 F.3d 1 (1st Cir. 2000). Thus, industrial hemp plants themselves are controlled under Schedule I.

The CSA definition of "Marihuana," however, explicitly provides that:

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

21 U.S.C. §802(16) (emphasis added).

The express language of the CSA thus provides that hemp oil, cake and sterilized seed are not controlled as "Marihuana" under Schedule I of the CSA. 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. Petitioners and all other companies who have been making products with hemp oil, cake or sterilized 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 its "Interpretive Rule," that Congress adopted this express exclusion because Congress may not have been aware of the "possibility that portions of the cannabis plant excluded from the definition of marijuana might contain THC." "Interpretive Rule," 66 Fed. Reg. at 51531. However, Congress was clearly aware that

the resin contained the drug element of Cannabis, since the resin itself is covered by the law. That Congress was not concerned that non-significant trace residual resin on the seeds themselves could ever be extracted and concentrated does not mean that Congress was unaware trace residual resin could unavoidably adhere to the seed coat. In any event, the statutory language expressly exempting hemp seed and oil is clear and unambiguous, and DEA does not contend otherwise. In these circumstances, speculation about legislative intent is irrelevant.[2]

CSA 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). Thus, it is clear that "THC", as used in CSA Schedule I, does not refer to the organic, naturally-occurring THC found in hemp oil, cake and sterilized seed, but only to synthetic THC. This construction was recognized in United States v. McMahon, 861 F.2d 8 (1st Cir. 1988). In that case, 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. 1976). In Wuco, the U.S. Department of Justice conceded that the listing of "Tetrahydrocannabinols" in Schedule I is limited to synthetic THC; this Court agreed that

[2] Indeed, DEA has long been aware that hemp seeds contain miniscule trace amounts of natural THC but has not previously attempted to nullify the Congressional exemption of hemp seed from the CSA. Susan Miller, a forensic scientist employed by DEA, clarified in an Affidavit on April 11, 1991, that despite the

"organic THC . . . is not the synthetic THC defined as a Schedule I controlled substance." Id. at 1202. Thus, it is clear from the statutory language of the CSA that "THC" as set forth in CSA Schedule I does not include the miniscule trace organic THC occurring in non-psychoactive hemp oil, cake and sterilized seed.[3]

DEA takes issue with this analysis, claiming that its regulations were always intended to include both naturally-occurring and synthetic THC, that the McMahon court erred and that no other court has ever definitively addressed the issue. "Interpretive Rule," 66 Fed. Reg. at 51531-34.[4] Whatever the merits of DEA's position, however—and those merits are not at issue here—the fact is that this "interpretation" works a complete change in the existing substantive law. It treats as illegal controlled substances hemp oil and seed, and oil and seed products, that were not illegal prior to the "interpretation."

That hemp oil, cake and sterilized seed were not controlled by the CSA prior to the "Interpretive Rule" Schedules has been confirmed by the Criminal Division of the U.S. Department of Justice, of which DEA, of course, is a part. In a letter to the DEA Administrator dated March 23, 2000, attached hereto as Exhibit 11, John Roth, Chief of the Narcotic and Dangerous Drug Section of the Criminal Division of the U.S.

"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."

[3] To be sure, as noted, pure naturally-occurring THC, refined from the flowers and resin of marijuana, would certainly be controlled under the definition of "Marihuana", as a derivative of the resin. Thus, there is no current or potential class of substances capable of abuse that is not already covered by the definitions of "Marihuana" and synthetic THC.

[4] DEA asserts that the explicit exemption by Congress of hemp oil, cake and sterilized seed from the CSA is effectively a nullity by virtue of DEA's "interpretation" of THC to include trace amounts of naturally-occurring THC. By this reasoning, DEA could "interpret" the CSA to include poppy seeds (most commonly consumed on bagels), which are explicitly exempted from the CSA in the statutory definitions of "opium poppy" and "poppy straw," 21 U.S.C. §§802(19), (20), based on the fact that poppy seeds contain trace amounts of natural opiates, with no present abuse potential, but that are in themselves clearly and unambiguously controlled under CSA, Schedule II(a)(1), 21 U.S.C. §812(c). This dichotomy shows again why the "interpretation" is a substantive change requiring formal rulemaking.

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

> Therefore, products derived from this portion of the cannabis plant commonly referred to as "hemp" are explicitly excluded from regulation under the Controlled Substances Act.
>
> It has been suggested that "hemp" products containing THC are subject to regulation under 21 U.S.C. §812(17). However, 21 U.S.C. §812(17) refers only to synthetic THC, not the THC naturally occurring within marijuana. The pertinent regulation, 21 C.F.R. §1308.11(d)(27), defines THC as "synthetic equivalent of the substances contained in the plant. . . ."
>
> Thus, it appears we are not able to regulate or prohibit the importation of "hemp" products based on any residual or trace content of naturally occurring THC. . . .
>
> [I]t is our legal opinion that we presently lack the authority to prohibit the importation of "hemp" products, absent regulatory language that interprets, or legislative action to modify, the definition of marihuana contained in 21 U.S.C. §802(16).

(emphasis added).

2. The Requirements of the APA and CSA

The APA, 5 U.S.C. §553, requires that agency regulations be promulgated through advance notice of rulemaking with an opportunity for public comment. "When an agency promulgates regulations other than interpretative rules, general policy statements or rules for its own organization, the APA generally requires prior notice and comment." Flagstaff Medical Center, Inc. v. Sullivan, 962 F.2d 879, 885-86 (9th Cir. 1992). "The exceptions to section 553 will be 'narrowly construed and only reluctantly countenanced.'" Alcaraz v. Block, 746 F.2d 593, 612 (9th Cir. 1984)(citations omitted). When an agency promulgates a substantive rule in violation of APA section 553, the rule is invalid. E.g., Malone v. Bureau of Indian Affairs, 38 F.3d 433, 439 (9th Cir. 1994).

Section 553(c) of the APA 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). Thus, to add a new substance to a CSA schedule, the DEA must undertake a formal rulemaking process. 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.

3. The "Interpretive Rule" Is a Substantive, Legislative Rule

DEA contends, of course, that its "Interpretive Rule" is indeed an interpretive rule, exempt from the notice and comment requirements of section 553 of the APA. 66 Fed. Reg. at 51533. An agency's characterization of its action, however, is not dispositive; "[a]n agency cannot avoid the requirement of notice-and-comment rulemaking simply by characterizing its decision" as something other than substantive rulemaking. Yesler Terrace Community Council v. Cisneros, 37 F.3d 442, 449 (9th Cir. 1994).

This Court has explained that "Interpretive rules 'simply clarify or explain existing law or regulations.' . . . They do not conclusively affect the rights of private parties." Yesler, 37 F.3d at 449, quoting Linoz v. Heckler, 800 F.2d 871, 877 (9th Cir. 1986). "Substantive rules, in contrast, create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress." Yesler, 37 F.3d at 449; accord, Linoz, 800 F.2d at 877. A rule that affects a change in agency policy, even one with substantial impact on regulated individuals or entities, does not necessarily constitute a legislative rule. Chief Probation Officers of Cal. v. Shalala, 118 F.3d 1327, 1335-36 (9th Cir. 1997). If an "interpretation" or policy is promulgated "pursuant to legislative power delegated by Congress—rather than [the agency's] own interpretive power over a congressional enactment--. . . the resulting rule, *a fortiori*, was legislative." Id. at 1336. Further, if a new rule is inconsistent with a preexisting legislative regulation, the new rule is itself a legislative rule that cannot be "immune from APA notice and comment." Id. at 1336-37.

In this case, it is clear that DEA's "Interpretive Rule" is, as a matter of law, a legislative rule. To be sure, DEA contends that its "Interpretive Rule" is being issued to address "public inquiries regarding the interpretation of the CSA." 66 Fed. Reg. at 51530. But the "interpretation", first of all, does not "merely clarify or explain" existing law and regulations. To the contrary, it "conclusively affects the rights of private parties," Yesler, 37 F.3d at 449, by rendering unlawful business activity that was previously lawful.

Second, the "interpretation" indeed "effect[s] a change in existing law pursuant to authority delegated by Congress." Id. That much is made clear by the fact that DEA has issued a proposed regulation which accomplishes exactly the same change in law that is effected by the "Interpretive Rule"—that is, putting on Schedule I any product that contains any amount of THC, even if such THC is naturally occurring in parts of the cannabis plant excluded from the CSA definition of "marijuana." In the Proposed Rule, that change in law is effectuated through an amendment of the actual language of DEA's regulations. See Exhibit 2 hereto, 66 Fed. Reg. at 51538, amending 21 C.F.R. §1308.11—Schedule I. And DEA is explicitly promulgating that amended regulatory language rule pursuant to legislative authority delegated by Congress: "This proposed rule is being issued pursuant to 21 U.S.C. 811, 812 and 871(b). Sections 811 and 812 authorize the Attorney General to establish the schedules in accordance with the CSA and to publish amendments to the schedules. . . ." Proposed Rule, Exhibit 2 hereto, 66 Fed. Reg. at 51535. When an agency "promulgated the rule pursuant to legislative power delegated by Congress—rather than its own interpretive power over a congressional

enactment--. . . the resulting rule, *a fortiori*, was legislative." Chief Probation Officers, 118 F.3d at 1336.

Finally, the "Interpretive Rule" is clearly inconsistent with the pre-existing legislative regulation, namely, DEA's own Schedule I regulation which on its face, as interpreted by the U.S. Department of Justice and as applied, excluded from Schedule I hemp oil and seed with trace amounts of naturally-occurring THC. Surely neither DEA, nor any agency, can be heard to claim that it is merely "interpreting" an existing legislative regulation by substantively changing that existing regulation, having the force of law, to criminalize previously lawful conduct. Indeed, were the "Interpretive Rule" not in fact a legislative rule inconsistent with the existing legislative rule, it would not have been necessary for DEA to promulgate its special "Interim Rule" exempting certain products from the "Interpretive Rule" and providing a grace period for affected companies to dispose of their existing inventories of non-exempt hemp seed and oil, and seed and oil products.

For these reasons, the "Interpretive Rule" is in fact a substantive, legislative rule that has been issued by DEA in violation of section 553 of the APA. Moreover, because DEA has in effect placed on Schedule I substances not previously included on that schedule, it has also violated the CSA's requirement that such a scheduling rule be adopted through formal rulemaking, on the record after opportunity for a hearing.

Because the rule was adopted in violation of the APA and the CSA, 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 "Interpretive Rule," the individual Petitioner companies will suffer irreparable injury, because their business activities have been instantly rendered unlawful. These companies must shut down their operations relating to importation, manufacture and sale of processed hemp seed and oil, and oil and seed food, nutritional and beverage products, or face the risk of criminal prosecution. See Roulac Dec., Exhibit 4 hereto at ¶ 9 (the "Interpretive Rule" "threatens to immediately shut down our entire hemp foods business. . . . and force us almost immediately to go out of business"); Hickey Dec., Exhibit 5 hereto at ¶¶ 8-9 (the rule "threatens to immediately shut down our entire business involving" a new hemp milk and also "threatens our company's investment of over $2 million"); Crew Dec., Exhibit 6 hereto, at ¶ 10 (rule "threatens to immediately shut down a significant portion of our entire business involving hemp food products'); Slagh Dec., Exhibit 8 hereto at ¶ 10 (rule "threatens to immediately shut down a significant portion of our entire business involving hemp food products"); Laprise Dec, Exhibit 9 hereto at ¶9 "interpretive" rule "threatens to immediately shut down our business involving hemp nuts, oil, meal and toasted seed. This action seriously threatens our business to the point that we may need to shut down our operations and force us to go out of business"); Stephens Dec., Exhibit 10 hereto at ¶ 8 (rule "threatens to immediately shut down our entire hemp foods business and thus threatens not only our company's revenue but several jobs at our Blaine, WA plant. . . . I have already received nervous telephone calls from longstanding customers who are considering dropping our Hemp Plus products based on the possibility that the new regulations will remain in effect"). Any relief ultimately afforded by this Court, if DEA's

"Interpretive Rule" were ultimately ruled invalid, would come too late to save the business operations of these companies.

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; some companies may well be forced out of business altogether, as the attached Declarations show. See section IV(B), supra. Petitioners' customers have already shown signs of discontinuing their purchases of edible hemp products from Petitioners in anticipation of the DEA regulations. See Roulac Dec., Exhibit 4 hereto at ¶ 9; Stephens Dec., Exhibit 10 hereto at ¶8. 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 Roulac Dec., Exhibit 4 hereto at ¶ 4. Jobs and livelihoods may well be lost during the pendency of this Court's review of the DEA's rule, if no stay is granted.

On the other hand, it is clear that DEA will suffer no hardship from a stay. As noted above, DEA announced its intention to promulgate the "Interpretive Rule," together with the "Proposed Rule" and "Interim Rule," almost a year ago. Dept. of Justice Annual Regulatory Agenda, 65 Fed. Reg. 74004 (Nov. 30, 2000). Obviously, having waited almost 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 on Schedule I of the CSA. Nor does DEA claim, in the "Interpretive Rule," that there is any such threat, or offer any other

policy rationale for making the "Interpretive Rule" effective immediately without notice or opportunity for comment.

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 "Interpretive Rule" pending this Court's review of that rule.

To the extent deemed appropriate by the Court, Petitioners request an opportunity to present oral argument on this Motion.

Respectfully submitted,

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Dated: October 19, 2001