UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 03-71336
No. 03-71603

HEMP INDUSTRIES ASSOCIATION, ET AL.

v.

DRUG ENFORCEMENT ADMINISTRATION, ET AL.

PETITION FOR REVIEW OF RULES OF
DRUG ENFORCEMENT ADMINISTRATION

BRIEF OF PETITIONERS

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STATEMENT OF JURISDICTION

(a) This is a Petition for Review of (i) the "Final Rule—Clarification of List of 'Tetrahydrocannabinols' in Schedule I," issued by respondent Drug Enforcement Administration ("DEA") on March 18, 2003, DEA-205F, 68 *Fed. Reg*. 14114 (March 21, 2003)("Rule 205F"), Excerpts of Record ("ER") at 23; and of (ii) the "Final Rule—Exemption from Control of Certain Industrial Products and Materials Derived from the

Cannabis Plant," issued March 18, 2003, DEA-206F, 68 *Fed. Reg*. 14119 (March 21, 2003)("Rule 206F"), ER at 28. DEA purported to issue Rule 205F and Rule 206F pursuant to the Controlled Substances Act ("CSA"), 21 U.S.C. §§811, 812 & 871(b).

(b) This Court has jurisdiction of this petition under section 507 of the CSA, 21 U.S.C. §877, which provides that any person aggrieved by a final decision of the Attorney General under the CSA "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." Petitioners Hemp Industries Association, All-One-God-Faith, Inc. d/b/a Dr. Bronner's Magic Soaps, and Atlas Corp. have their principal places of business in California, within this Circuit.

(c) Rule 205F and Rule 206F were both issued by DEA on March 18, 2003. Petitioners timely filed their Petition for Review on March 28, 2003. 21 U.S.C. §877; Fed. R. App. P. 15(a)(1).

ISSUES PRESENTED FOR REVIEW

1. Is Rule 205F invalid because it represents the scheduling of new substances—hemp stalk, fiber, seed and oil—in Schedule I of the CSA,

without DEA having conducted a formal rulemaking on the record after opportunity for hearing or having made the specific findings required by the CSA for such scheduling, 21 U.S.C. §811(a)?

2. Is Rule 206F contrary to law because DEA exercised its authority, under section 811(g)(3)(B) of the CSA, to exempt certain substances from control, in an arbitrary and capricious manner?

3. Is Rule 205F invalid because DEA failed to comply with the Regulatory Flexibility Act, 5 U.S.C. §605(b)?

STATEMENT OF THE CASE

Petitioners are companies that manufacture, distribute and/or sell, in the U.S., 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 (soaps, shampoos, lotions, etc.).[1] Such seed, oil or products contain non-psychoactive miniscule trace amounts of residual resin, which contain naturally occurring tetrahydrocannabinols ("THC"). Such THC is generally too trace and insignificant to be detected by ordinary lab analysis, but nonetheless can be detected given powerful enough detection

[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. Other Petitioners are major hemp food and body care companies and consumers. The businesses of the other Petitioners are described in detail in the Declarations attached to Petitioners' Urgent Motion for Stay Pending Review, filed March 28, 2003.

equipment and protocols.[2] 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), ER at 12. This "Interpretive Rule," made effective immediately 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*.

[2] The statements of the Hemp Food Association, a promotional vehicle of HempNut Inc., are relied on by DEA to the effect that this company's products contain no THC. Rule 205F, ER at 27 & n. 17. Those statements are baseless. Trace amounts of THC were actually found in HempNut's own products shortly after HempNut resigned from the hemp industry's TestPledge program. The Hemp Food "Association" does not represent or speak for any hemp food company other than the one firm, HempNut, Inc. See Declaration of Candi Penn (Executive Director of HIA), attached to Petitioners' Urgent Motion for Stay Pending Review, filed March 28, 2003 in this docket.

51535 (Oct. 9, 2001)("Proposed Rule"), ER at 13. The "Proposed Rule" proposed to 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 trace THC-containing hemp product to dispose of such product. 66 *Fed. Reg*. 51539, 51543 (Oct. 9, 2001), ER at 17.

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.

In the meanwhile, DEA proceeded with its rulemaking under the October 2001 Proposed Rule (identical to the "Interpretive Rule"), affording opportunity for public comment. On December 10, 2001, Petitioner HIA and a number of its member companies timely submitted comments on the Proposed Rule.

On March 21, 2003, DEA published Rule 205F and Rule 206F. Rule 205F amends DEA's 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, fiber, 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 Rule 206F, making final its earlier "Interim Rule"—that is, exempting from control trace THC-containing hemp stalk, fiber, seed and oil products as long as they cannot be used 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 (Rule 206F, 68 *Fed. Reg*. at 14121-22, ER at 30-31), 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 would be rendered unlawful by Rule 205F, which was to become effective by its terms 30 days after its issuance.

On March 28, 2003, Petitioners filed their Petition for Review of Rules 205F and 206F, together with an Urgent Motion for Stay Pending Review. On April 16, 2003, the Court issued an order granting Petitioners' Urgent Motion to Stay Rule 205F pending the Court's review of the Petition for Review in this case.

In the meantime, on April 7, 2003, the Court issued an Order requiring the petitioners in No. 01-7166 (the Petition for Review of the "Interpretive Rule") to show cause why that appeal is not moot.

STATEMENT OF FACTS

Industrial hemp is a commonly used term for non-psychoactive varieties of the species Cannabis sativa L. that are cultivated for industrial rather than drug purposes. Industrial hemp plants grown in Canada and Europe are bred to contain less than 0.3% and 0.2% by weight of THC in the upper portion of the flowering plant, respectively, versus marijuana varieties which typically contain 3 to 15% THC in their flowers.[3] Due to minimal THC content, flowers from industrial hemp have no potential for drug use. Hemp 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"), ER at 42.

As explained below, the statute controlling "marihuana" has, since 1937, excluded hemp stalk, fiber, seed and oil, except the resin therefrom.[4] This statutory exclusion has enabled U.S. individuals and businesses to legally purchase, use, and trade in sterilized hemp seeds, oil, stalk and fiber,

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

[4] Congress in the 1970 CSA directly incorporated the definition of "marihuana" from the 1937 Marihuana Tax Act.

and products made therefrom. Hemp food, oil and fiber products are available throughout the U.S., Canada, the European Union and Asia. The companies currently selling hemp seed and oil food, nutritional and personal care products in the U.S., including the Petitioners, generally either import hemp seed and oil from Canada or Europe, for use in manufacturing these products in the U.S., or import already finished products from Canada or Europe.

Hemp seed is botanically an "achene" or small nut. Seeds are separated and cleaned; oil is predominantly extracted through a mechanical "cold pressing" process. *See* Thompson, Berger & Allen, ECONOMIC IMPACT OF INDUSTRIAL HEMP IN KENTUCKY 5 Fig. 1 (Univ. of Kentucky Center for Business & Economic Research, July 1998)("Kentucky Study"), ER at 95. Most of the seed's value is derived from either dehulling the whole seed and/or crushing it for oil.

According to the USDA Study, "Hemp seeds can be used as a food ingredient or crushed for oil and meal. The seed contains 20 percent high-quality digestible protein, which can be consumed by humans. . . The oil can be used both for human consumption and industrial applications." USDA Study at 15, ER at 49. The oil content of hemp seeds varies from 30% to 40%. Hemp seed oil typically contains 75-80% of the poly-unsaturated

essential fatty acids (EFA's) that are needed by, but not naturally produced by, the human body. I. Bocsa and M. Karus, THE CULTIVATION OF HEMP: BOTANY, VARIETIES, CULTIVATION AND HARVESTING 38 (1998). According to the Kentucky Study, the basic reasons for use of hemp oil in foods are that "hemp oil has a better profile of key nutrients, such as essential fatty acids and gamma-linolenic acid, than other oils,. . . and a similar profile of other nutrients, such as sterols and tocopherols." Kentucky Study at 7-8, ER at 97-98. In particular, hemp seed and oil provide a significant dietary source of omega-3 fatty acid without the trace mercury and other environmental toxins present in traditional fish oil omega-3 supplements.

This superior nutritional profile makes hemp seed and oil ideal for a wide range of food applications. Hulled hemp seeds, or hemp nuts, resemble sesame seeds in appearance and are comparable to sunflower seeds in taste. They may be incorporated in baking or simply added to foods such as soups or salads. Consumption of hemp nuts blended in shakes or drink mixes offers an alternative to meet both daily protein and EFA needs. Hemp nuts may be ground and turned into nut butter for spreads and sandwiches. In the U.S., research is being conducted to use hulled or whole hemp seeds in the production of "hemp milk" as an alternative to soy or rice based non-dairy milks, a category that is now the largest selling in the natural foods business.

The USDA study identifies food products containing hemp ingredients to include roasted hulled seed, nutrition bars, tortilla chips, pretzels and beer. USDA Study at 3, ER at 38. Firms have also attempted to develop products including cheese, margarine and candy bars. Kentucky Study at 7, ER at 97. 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).

Hemp oil is also used in a variety of cosmetic and body care products manufactured and/or distributed in the U.S., including bar and liquid soaps, shampoos and hair conditioners, body lotions, creams, massage oils, lip balms and salves. (USDA Study at 3, 17, ER at 38, 51). The polyunsaturated fatty acid contained in the oil may help to alleviate dry-skin defects, such as cracking and scaling, improve the smoothness of dry and scaly skin and slow down skin aging and the formation of wrinkles. B. Idson, "Dry skin: moisturizing and emolliency," 107 COSMETICS AND TOILETRIES 69-78 (1992).

Hemp nut (i.e. the meat of the seed) itself contains only miniscule traces of THC, usually much less than 0.5 parts per million (ppm, equivalent to microgram per gram - μg/g) of THC; however, the "[p]resence of THC in

hemp seed products is predominantly caused by external contact of the seed hull with cannabinoid-containing resins in bracts and leaves during maturation, harvesting, and processing." Leson, Pless, Grotenhermen, Kalant and ElSohly, *Evaluating the Impact of Hemp Food Consumption on Workplace Drug Tests*, 25 JOURNAL OF ANALYTICAL TOXICOLOGY 691, 692 (Nov./Dec. 2001).

Consequently, hemp oil may contain trace amounts of THC from the trace resin residue on the outer shells. *See* Ross *et al*., GC/MS ANALYSIS OF THE TOTAL DELTA-9-THC CONTENT OF BOTH DRUG AND FIBER TYPE CANNABIS SEEDS (2000). "Since 1998, more thorough seed drying and cleaning appears to have considerably reduced THC levels in seeds and oil available in the U.S." Leson, Pless, Grotenhermen, Kalant and ElSohly, *supra*, at 692. Currently, THC levels in hulled seeds produced in Canada are typically less than 2 ppm and in hemp seed oil, 5 ppm, which are "sufficiently low to prevent confirmed positives [in urine drug-testing for marijuana] from the extended and extensive consumption of hemp foods." Leson, Pless, Grotenhermen, Kalant and ElSohly, *supra* at 691.[5]

[5] The hemp industry's "TestPledge" program, based on this study, is intended to alleviate consumer concerns regarding workplace drug-testing interference, even with unrealistically extensive daily consumption of hemp nut and oil. *See* Exhibit 2 to Reply of Petitioners in Support of Urgent Motion for Stay Pending Review, filed April 14, 2003.

SUMMARY OF ARGUMENT

The CSA expressly exempts hemp stalk, fiber, seed and oil from the definition of "Marihuana," notwithstanding that such stalk, fiber, seed and oil may contain non-psychoactive miniscule naturally occurring trace amounts of THC. Rule 205F is based on DEA's contention that, having specifically excluded hemp stalk, fiber, seed and oil from the definition of "marihuana," Congress nevertheless intended to include them in the definition of "THC" if they contain *any* THC at all, no matter how trace and insignificant. In fact, the term "THC" in the statute refers only to synthetic THC. But even if it covered naturally-occurring THC, DEA's position would simply read the express exclusion out of the statute. The exclusion would be rendered utterly superfluous.

Rule 205F is not entitled to *Chevron* deference because the language of the statute is absolutely clear: Congress exempted hemp stalk, fiber, seed and oil despite the presence of trace insignificant amounts of THC-containing resin. The language of the statute, on its face, indicates congressional knowledge that the trace resin contains the active drug principle, formally identified as THC in the 1960's. Despite that knowledge, Congress determined to exempt hemp stalk, seed, fiber and oil. The plain meaning of the statute must control. But even if the Court were to proceed

to the second step of the *Chevron* analysis, reading the statutory exclusion of hemp out of the statute is not a permissible construction.

Since the CSA, Schedule I, currently does not include hemp seed, stalk, fiber or oil, DEA's rulemaking placing those substances on the Schedule is a scheduling action governed by sections 811 and 812 of the CSA. Under section 812(b), substances cannot be listed on Schedule I unless certain specific findings are made by DEA. Under section 811, any scheduling must be undertaken as a formal rulemaking, on the record with opportunity for a hearing. DEA did not make any of the required findings or hold the required hearing. For that reason, Rule 205F is invalid.

Even if Rule 205F were valid, Rule 206F would not be. That rule purports to exempt any material or animal feed containing trace THC, but not used or intended for use for human consumption. DEA has no specific authority to exempt animal feed, but determined to do so anyway for two reasons: (1) the legislative history of the 1937 Marihuana Tax Act shows Congress intended to allow hemp animal feed and (2) there is less potential for abuse than in a product intended for human use. Both of these reasons, however, apply with equal force to most if not all of the hemp seed and oil products that DEA did *not* exempt in Rule 206F. The legislative history of the 1937 Act makes clear that Congress expressly contemplated and allowed

all hemp oil, fiber, stalk and sterilized seed (except the trace resin extracted therefrom)—not just animal feed. And DEA utterly fails to explain why it believes that the potential for abuse is less in animal feed than in a product intended for human consumption; indeed the agency made no findings about the potential for abuse of any edible hemp seed or oil product containing infinitesimal trace amounts of natural THC.

DEA is not required to exempt any substance that is properly placed on a CSA Schedule to begin with. But if the agency chooses to exercise exemption authority, it cannot do so in an arbitrary and capricious way. In this case, DEA's failure to treat edible hemp seed and oil products in the same way as animal feed—even though the factors of legislative history and potential for abuse dictate exactly the same treatment-- is completely unsupported, unexplained and, therefore, arbitrary and capricious.

Finally, DEA violated the Regulatory Flexibility Act in issuing Rule 205F, because it did perform a regulatory flexibility analysis, but failed to adequately assess the economic impacts or explain why alternatives to the rule were rejected by the agency.

ARGUMENT

I. RULE 205F IS A SCHEDULING OF HEMP STALK, FIBER, SEED AND OIL UNDERTAKEN IN VIOLATION OF THE REQUIREMENTS OF THE CONTROLLED SUBSTANCES ACT

Rule 205F legally represents a scheduling action under and subject to the CSA, 21 U.S.C. §811. Under the CSA, section 812(b), substances cannot be listed on Schedule I of the CSA unless certain specific findings are made by DEA. Further, the CSA, section 811(a), requires that any scheduling be undertaken as a rulemaking on the record after opportunity for hearing, pursuant to the formal rulemaking procedures of the Administrative Procedure Act, 5 U.S.C. §§556-57. DEA failed to hold any hearing or make any of the required findings. For that reason, Rule 205F is invalid.

A. Petitioners' Products Were Not Controlled Substances Prior to Issuance of Rule 205F

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 Rule 205F.[6]

[6] 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.

The basic reason is that the CSA exempts hemp stalk, fiber, seed and oil from the definition of "Marihuana", notwithstanding that such stalk, fiber, seed and oil may contain non-psychoactive miniscule trace amounts of residual resin with naturally-occurring trace amounts of THC. DEA's position, as reflected in Rule 205F, is that, having expressly excluded hemp stalk, fiber, 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.[7] This position is contrary to the plain language of the statute and makes no sense.

1. Hemp Stalk, Fiber, Seed and Oil Are Not Controlled as "Marihuana"

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.*

[7] DEA's Rule 206F re-exempts hemp fiber and seed products from control if they cannot be used for human consumption, but Rule 205F itself bans hemp rope, paper, twine and clothing along with hemp stalks and foods insofar as trace THC is present in such fiber products.

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, fiber, oil, and sterilized seed are *not* controlled as "Marihuana" under Schedule I of the CSA. In fact, the express exclusion of hemp stalk, fiber, oil 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.,* U.S. Senate Finance Committee, Hearings on H.R. 6906, 7th Cong., 1st Sess. (1937). The 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.

2. Hemp Stalk, Fiber, Seed and Oil Are Not Controlled as THC

DEA argues, in Rule 205F, that the statutory listing of "Tetrahydrocannabinols" in Schedule I was made without distinction between naturally occurring and synthetic THC, and that hemp stalk, fiber, seed and oil—despite the express statutory exclusion—can therefore simply be regulated as THC if they contain any trace THC whatsoever. 68 *Fed. Reg*. at 14114-15, ER at 23-24. Indeed, DEA contends that its rule actually "does not change the legal status of so-called 'hemp' products", *id*. at 14114, ER at 23, 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 tetrahydrocannabinols to be a schedule I controlled substance. This interpretation holds regardless of whether the product in question is made from 'hemp'….

Id. at 14115, ER at 24.

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, is defined by DEA's prior regulation (i.e. before issuance of the October 2001 "Interpretive Rule") as "*synthetic equivalents* of the substances contained in the plant, or in the resinous extractives of Cannabis, sp., and/or synthetic substances derivatives and

their isomers…" 21 C.F.R. §1308.11(d)(27) (emphasis added).[8] That regulation recognized that the plain statutory language simply does not refer to the trace organic, naturally-occurring THC found in hemp stalk, oil, fiber 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)(10) 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.

[8] DEA itself in its "Interpretive Rule" states that prior to the CSA, "THC" under the regulations of the Bureau of Narcotic and Dangerous Drugs (BNDD) meant synthetic THC only, and that "Marihuana" under the 1937 Tax Act controlled natural THC as an extract of the resin. 66 *Fed. Reg.* at 51532, ER at 10. The same language of the BNDD regulations carried forward into the DEA's regulation of THC, as referring to "synthetic equivalents" only, not natural.

3. The Statute On Its Face Precludes Treatment of Hemp Stalk, Fiber, Seed and Oil as THC Notwithstanding the Presence of Trace Amounts

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, fiber, 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, fiber, 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 stalk, fiber, oil and sterilized seed itself exempts—and thus brings back under control—the "resin extracted therefrom." 21 U.S.C. §802(16). Congress thus knew and understood that the stalk, fiber, seed and oil might contain some THC-containing resin, based on the plain language of the definition.

Congress nevertheless exempted hemp stalk, fiber, seed and oil from the definition of "Marihuana" while prohibiting the extraction and concentration of resin from such stalk, fiber, seed and oil. Indeed, Susan Miller, a forensic scientist employed by DEA, clarified in an Affidavit on April 11, 1991, ER at 104, 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."[9]

Further, 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, fiber, seed and oil *are* "specifically excepted" right in Schedule I of the CSA.

DEA's position, reflected in Rule 205F, is that, despite the explicit statutory exclusion, hemp stalk, fiber, seed and oil are simply covered by the definition of THC as any "material compound, mixture" which "contains any quantity of" THC. Rule 205F, 68 *Fed. Reg*. at 14115, ER at 24, quoting CSA Schedule I(c)(17). Surely that logic proves too much, however, for if excluded parts of a plant were nonetheless to be included in any "material, compound, mixture or preparation" containing any controlled substance, then poppy seed bagels would be controlled substances as "narcotic drugs," 21 U.S.C. §802(17). Even though the seeds are exempted by statute, 21 U.S.C. §802(19), poppy seed bagels are literally a "compound, mixture, or

[9] Similarly, in an April 18, 1991 affidavit, ER at 101, Charles M. Metcalf, a senior investigator for the DEA, stated: "The DEA does not consider sterile marijuana seed …to be a controlled substance, whether or not it contains residue or particulate matter which tests positive for the presence of THC."

preparation which contains any quantity" (21 U.S.C. §802(17)(F)) of opiates (*id*. §802(17)(A)).

Indeed, contrary to DEA's contention (68 *Fed. Reg*. at 14116, ER at 25), 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, do not bring those seeds under control given that Congress has specifically exempted them.

DEA's position would effectively read the express exclusion of hemp stalk, fiber, seed and oil right out of the statute. "The meaning of statutory language, plain or not, depends on context. . . . Context in this regard relates to 'the design of the statute as a whole and to its object and policy.'" *Brower v. Evans*, 257 F.3d 1058, 1065 (9th Cir. 2001)(citations omitted). Thus, "in 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), *pet. cert. filed* May 2, 2003, *quoting 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, fiber, oil and seed from one part of Schedule I only to provide that another part of Schedule I covers hemp stalk, fiber, oil and seed?

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

That hemp stalk, fiber, 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 a letter to the DEA Administrator dated March 23, 2000, ER at 99 (that was a duplicate of a letter sent to the Commissioner of Customs a day earlier), 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, fiber, 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).

B. Rule 205F Is Not Entitled to Chevron Deference

Under *Chevron*, "We must first determine whether Congress has directly spoken to the precise question at issue…. 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." *CHW West*

Bay v. Thompson, 246 F.3d 1218, 1223 (9th Cir. 2001), *quoting Chevron USA, Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 843 (1984). In this case, Congress has indeed spoken to the precise question and the statute is absolutely unambiguous: Congress has exempted hemp stalk, fiber, seed and oil from the definition of "Marihuana," notwithstanding the presence of trace insignificant amounts of resin, which THC-containing resin is itself already controlled to the extent it is extracted and concentrated in any way. 21 U.S.C. §802(16).

DEA's "interpretation" is thus not really an interpretation at all. It is a conclusion that Congress, having expressly *excluded* hemp stalk, fiber, seed and oil from one term listed in Controlled Substances Act Schedule I—Marihuana--nevertheless intended to *include* them in the definition of another term, "THC"—even though that other term ("THC") appears in the *same* part of the *same* Schedule as "Marihuana." CSA Schedule I(c). If DEA's position were accepted, the exclusion would thus be rendered absolutely meaningless.

That is not an "interpretation" of the CSA; it is simply an effort to read the exclusion out of the statute—to flatly ignore the express provision in section 802(16) legalizing hemp stalk, fiber, seed and oil. "In the statute at issue, Congress left no gap, no silence no ambiguity, so 'we must give

effect to the plain language that Congress chose.' . . . .The regulation is contrary to the will of Congress as expressed in the governing statute." *Orca Bay Seafoods v. Northwest Truck Sales, Inc*., 32 F.3d 433, 437 (9th Cir. 1994), *quoting U.S. v. Geyler*, 949 F.2d 280, 283 (9th Cir. 1991).

Even if this Court were to proceed to the second step of the *Chevron* analysis, it is clear that reading the exclusion of hemp stalk, fiber, seed and oil out of the statute is simply not a "permissible construction." *Chevron*, 467 U.S. at 843. "In reviewing an agency's statutory construction, we must reject those constructions that are contrary to clear congressional intent or frustrate the policy that Congress sought to implement." *Brower, supra*, 257 F.3d at 1065. Manifestly, ignoring the express statutory exclusion for hemp stalk, fiber, seed and oil would be "contrary to clear congressional intent" to exempt those substances from control. "[S]tatutes must be interpreted, if possible, to give each word some operative effect." *Walters v. Metro Educational Enterprises, Inc.,* 519 U.S. 202, 209 (1997). By contrast, DEA's rule is a "violation of the bedrock principle that statutes not be interpreted to render any provision superfluous." *Environmental Defense Ctr., Inc. v. Natural Resources Defense Council, Inc*., 319 F.3d 398, 409 (9th Cir. 2003). For these reasons, DEA's rule is not entitled to *Chevron* deference.

C. Rule 205F 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." Rule 205F, 68 *Fed. Reg*. at 14116, ER at 25.

The issue, however, is not whether THC is being scheduled, or rescheduled, but whether *hemp stalk, fiber, seed and oil* are being scheduled. Because hemp stalk, fiber, seed and oil are not currently covered by any schedule of the CSA, Rule 205F clearly constitutes a scheduling action—that is, putting new substances on Schedule I of the CSA.[10]

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[10] DEA claims that, absent Rule 205F, 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 non-controlled substance." 68 *Fed. Reg*. at 14114, ER at 23. Such a hypothetical situation has never occurred in the United States, which is not surprising since such extraction would be technically and economically unfeasible. But even if such an extract were produced, it would automatically be controlled: 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 allegedly psychoactive Swiss salad oil referred to in Rule 206F, 68 *Fed. Reg*. at 14123, ER at 32, 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

Since the CSA schedules essentially impose rules for handling controlled substances, one measure of whether any substance has been "scheduled" for CSA purposes is whether the rules for handling it have changed. Here, there is no question that the rules for handling hemp seeds, stalks, and oil have changed dramatically. While it was formerly legal to possess and use hemp seed, oil, and stalks since there were no restrictions on their use, it is now illegal to possess and use them. Further, Rule 205F also destroys all property rights both in Petitioners' raw materials and in their product inventory, because the CSA provides that "no property right shall exist" in controlled substances (as well as related raw materials, manufacturing equipment, conveyances, containers, books and records and monies) whose handling violates the CSA. 21 U.S.C. § 881(a). A more stark change in the rules for handling a substance is hard to imagine.

These facts also make clear that, in the absence of a scheduling proceeding, Rule 205F constitutes a taking without compensation and without a public purpose in violation of the Fifth Amendment. *Webb's Fabulous Pharmacies, Inc. v. Beckwith*, 449 U.S. 155, 163-64 (1980); *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1015 (1992); *Hawaii*

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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. The sole intent of DEA's rulemaking is to schedule the congressionally exempted non-drug substances hemp stalk, seed and oil.

Hous. Auth. v. Midkiff, 467 U.S. 229 (1984). And while DEA may be authorized to accomplish such takings for public purposes through the procedure set forth by Congress for a scheduling action, with all the public scrutiny and accountability for positions envisioned by that process, it is not authorized to do so without the specific findings that would establish a "public purpose." Accordingly, this Court should not credit DEA's assertion that it can accomplish its goal of making hemp stalk, seeds, and oil (or products made from them) into controlled substances without following the scheduling requirements of the CSA.

D. DEA Violated the 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 cupcakes--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, CSA 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*, *supra*, 846 F.2d at 543.

Nowhere in Rule 205F does DEA make any of the findings required by section 811(a) for hemp stalk, fiber, seed and oil. Because Rule 205F

was thus adopted in violation of the CSA's clear requirements, the rule is manifestly invalid.

II. RULE 206F IS ARBITRARY AND CAPRICIOUS BECAUSE IT TREATS LIKE SITUATIONS DIFFERENTLY WITHOUT ADEQUATE EXPLANATION OR BASIS

Even if Rule 205F were valid, Rule 206F is not. The latter rule exempts from regulation certain substances containing hemp stalk, fiber, seed or oil on grounds that apply equally to other substances that are not so exempted. For this reason, Rule 206F is arbitrary and capricious within the meaning of the Administrative Procedure Act, because the rule draws distinctions between like categories of products that are without any rational basis.

Rule 206F adds to DEA's regulations a new 21 C.F.R. §1308.35, which exempts from control any "processed plant material or animal feed mixture" containing any amount of THC, made from hemp stalk, fiber, sterilized seed or oil, and "[n]ot used, or intended for use, for human consumption." (The actual language of the new regulation appears in Interim Rule, 66 *Fed. Reg*. at 51544, ER at 22). DEA purports to issue Rule 206F pursuant to the agency's authority under 21 U.S.C. §811(g)(3)(B), which provides, in pertinent part, that DEA "may, by regulation, exempt any

compound mixture or preparation containing a controlled substance" if it finds that such compound, mixture or preparation—

> contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

A. DEA's Exemption of Animal Feed Is Based on Legislative History and Lack of Potential for Abuse

In Rule 206F, DEA explains that the rule exempts industrial hemp products such as paper, clothing and rope, since "[l]egitimate use of such products cannot result in THC entering the human body."[11] 68 *Fed. Reg*. at 14120, ER at 29. DEA then explains that Rule 206F also exempts animal feed containing hemp seed, as long as the seeds are mixed with other ingredients. *Id*. Personal care products, such as lotions and shampoos, made with hemp oil are exempt, *id*. at 14121, ER at 30, unless they are "formulated and/or designed to be used in a way that allows THC to enter the human body." Id. at 14122, ER at 30. All other hemp products that contain any amount of THC are *not* exempt and are controlled, including hemp oil itself (even if intended to be used in the U.S. manufacture of

[11] Although providing just as much risk to public health and safety as ingesting hemp foods with trace insignificant THC, DEA is evidently not concerned about trace THC present in hemp rope or paper entering the body in similarly infinitesimal quantities through rope abrasions and paper cuts.

personal care or cosmetic products) and "any food or beverage…" containing hemp seed or oil. *Id.*

In fact, DEA does not have statutory authority under section 811(g)(3)(B) to exempt animal feed, because in order to meet the requirements of that section, a compound or mixture must be "not for administration to a human being *or animal*…." DEA expressly acknowledges this lack of statutory authority, 68 *Fed. Reg*. at 14120, ER at 29. But DEA then states that it believes it is nevertheless "appropriate to exempt from application of the CSA animal feed mixtures containing such [hemp] seeds", *id*., under the agency's general authority under 21 U.S.C. §871(b), to promulgate any rules or regulations which the agency deems necessary and appropriate for the enforcement of the CSA.

DEA provides two reasons for its use of this general authority to exempt animal feed mixtures: (1) that "the legislative history of the 1937 Marihuana Tax Act reveals that Congress expressly contemplated allowing 'hemp' animal feed;", 68 *Fed. Reg*. at 14121, ER at 30; and (2) that the "presence of a controlled substance in animal feed poses less potential for abuse than in a product intended for human use." *Id*. Specifically, DEA claims, when sterilized hemp seed is mixed with other ingredients in animal feed, "there is minimal risk that they will be converted into a product used

for human consumption. Therefore, such legitimate use in animal feed mixture poses no significant danger to the public welfare." *Id*.

B. Products DEA Failed to Exempt Are Identical to Animal Feed With Respect to Legislative History and Potential for Abuse

1. Legislative History

The exact same two reasons, however, apply to most if not all of the hemp seed and oil products that DEA did not exempt—in particular, to edible hemp seed and oil products. First, the legislative history of the 1937 Marihuana Tax Act makes clear that Congress expressly contemplated allowing *all* hemp oil, fiber, stalk and sterilized seed—not just animal feed. The statutory exemption in the CSA, of course, is not limited to animal feed but applies to all hemp oil, fiber, stalk and sterilized seed. 21 U.S.C. §802(16). Further, the legislative history indicates that, although Congress was aware that hemp seed and oil contain trace amounts of a drug-containing resin (the active constituent of which, natural THC, was subsequently identified in the early 1960's), Congress nevertheless concluded that such trace amounts are not sufficient to be harmful, even when consumed by humans.

At hearings before the House Ways and Means Committee in April 1937, Clinton Hester, Assistant General Counsel for the Treasury

Department, testified that, "As the seeds, unlike the mature stalk, contain the drug, the same complete exemption could not be applied in this instance." Hearings on H.R. 6385, 7th Cong., 1st Sess. 8 (April 1937). Later, Dr. Herbert J. Wollner, consulting chemist for the Treasury Department, clarified for the Committee that:

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

Id. at 52-54 (emphasis added).

At the same time, the Ways and Means Committee heard considerable testimony to the effect that the very small amounts of the "active principle", i.e., THC, potentially present in hemp seed and oil—*even when consumed by humans*-- would not have any harmful effect or potential for abuse. Mr. Wollner testified, for example, that the "small amount of that resin" is indeed negligible and harmless and technically very difficult to extract and concentrate (and thus economically prohibitive):

> Mr. Buck [Rep. Frank Buck (D-Cal)]: Does the oil from the seed contain any of this deleterious matter?
> Mr. Wollner: That would in a large measure depend upon the condition of the seed and the condition of manufacture, but I would

> say in any event the oil would not contain a large amount of this resin….
> Mr. Buck: Would it contain enough to have any harmful effect on anyone, if taken internally?
> Mr. Wollner: I would say no; it would not contain such an amount.
> Mr. Fuller [Rep. Claude Albert Fuller (D-Ark.)]: As I understand it, you say the oil does not contain much, if any, of the drug?
> Mr. Wollner: It does contain some of the drug, but not much. It would appear, offhand, to be rather difficult to separate, but processes might possibly be developed for that purpose.
> Mr. Fuller: It would not be useful for the purpose for which they are using marihuana.
> Mr. Wollner: No.
> Mr. Fuller: So, so far as the oil from the seed is concerned, it is harmless, as far as human use is concerned.
> Mr. Wollner: That is right.

Id. at 54 (emphasis added). Similarly, during the testimony of Ralph Lozier, general counsel of the National Institute of Oilseed Products, before the Committee, the following exchange took place indicating congressional awareness of the insignificant harmless quantity of trace resin in the seed:

> Mr. Lozier: … No one will contend, or no respectable authority will assert, that this deleterious principle is found either in the seed or the oil….. . .If the committee please, the hemp seed, or the seed of cannabis sativa, L., is used in all the Oriental nations and also in a part of Russia as food. It is grown in their fields and used as oatmeal. Millions of people every day are using hemp seed in the Orient as food. They have been doing that for many generations, especially in periods of famines.
> Mr. Fuller: I do not think that the gentlemen who have presented the case on behalf of the committee, or the Government, have claimed that it was present in the oil.
> Mr. Lozier: They have said it was in the seed.
> Mr. Fuller: He said there was very little in the seed. He said there would be no injurious effect from the little there was in the seed.

Id. at 61 (emphasis added).

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

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

Id. at 3-4 (emphasis added).

Likewise, the Senate Finance Committee heard testimony making clear that hemp seed and oil contain trace amounts of resin (*i.e*. THC), but that these miniscule amounts would not have any harmful effect or be capable of abuse. In July 1937 hearings before the Finance Committee, Mr. Hester of the Treasury Department testified that:

> Mr. Hester: The flowering tops, leaves and seeds of the hemp plant contain a dangerous drug known as marihuana….
> Senator [Prentiss Marsh] Brown [(D-Mich.)]: Say you are in this situation. You have a plant that produces several articles that are valuable commercially.
> Mr. Hester: That is right.

> Senator Brown: At the same time, as a byproduct the leaves and the seeds can be used for marihuana?
> Mr. Hester: That is right.

U.S. Senate Finance Committee, Hearings on H.R. 6906, 7th Cong., 1st Sess. 9 (1937)(emphasis added). At the same time, the Finance Committee heard testimony from Matt Rens, of Rens Hemp Company of Brandon, Wisconsin, explaining that:

> No evidence has been obtained, either by scientific investigation or by practical observation to indicate that hemp seed, as handled in the trade, contains an appreciable proportion of the chemical substances which cause the narcotic effect. . . . A recent and thorough-going inquiry indicates that there are no biological tests or other researches which show that narcotic-producing substances are present in the seeds in a sufficient proportion to be harmful, in fact, there is nothing that shows that true seeds cause any of the narcotic effects. …
> The technical evidence given in the [House] hearings. . . shows that the seed does not contain an appreciable proportion of the narcotic substances. The [House] hearings also show that the seed was considered so harmless as to warrant omitting sterilized hemp seed from the definition of marihuana. . . . There is also no evidence, either practical or technical, to show that hemp seed has ever been used to produce the drug effect.

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

> The flowering tops, leaves, and *seeds* of the hemp plant contain a dangerous drug known as marihuana. . . .The term "marihuana" is defined so as to bring within its scope all parts of the plant having the harmful drug ingredient, but so as to exclude the parts of the plant in which the drug is not present.

S. Rep. 900, 75th Cong., 1st Sess. 1, 4 (1937) (emphasis added).[12]

Thus, the legislative history of the 1937 Act provides no basis whatsoever for distinguishing the animal feed that Rule 206F would exempt from the edible hemp seed and oil products that DEA declined to exempt.

2. Potential for Abuse

Second, DEA utterly fails to explain why it believes that "the presence of a controlled substance in animal feed poses less potential for abuse than in a product intended for human use…." Rule 206F, 68 *Fed. Reg*. at 14121, ER at 30. DEA has made *no* findings whatsoever about any potential for abuse of any edible hemp seed or oil products containing infinitesimal trace amounts of naturally occurring THC. More critically, in Rule 205F, DEA expressed—as a basis for issuing the rule—the agency's concern that "portions of the cannabis plant excluded from the CSA definition of marijuana"—i.e., hemp stalk and sterilized seed-- would be non-controlled

[12] DEA omits the opening phrase in their citation of the Senate Report to support their contention that Congress did not know about and did not explicitly allow and control for trace insignificant amounts of resin present in hemp stalk, fiber, seed and oil in making the exemption. DEA's contention is contradicted by the plain language of the statute itself.

substances. According to DEA:

> Anyone could then obtain this raw cannabis plant material to produce an extract of THC—all without legal consequence. This would give drug traffickers an essentially limitless supply of raw plant material from which they could produce large quantities of a highly potent extract…..

68 *Fed. Reg*. at 14114, ER at 23.

As noted above, such an extract would in fact be controlled, since the extract would necessarily be derived from the resin of the seeds and stalks, which is already specifically controlled under the CSA as "Marihuana"—as a derivative of the resin. But, more critically, the fact is that sterilized hemp seed mixed in animal feed is susceptible to this very same hypothetical "extraction" process. Such seed is "raw cannabis plant material," just like any other hemp seed; that it may be mixed with other ingredients would of course be no obstacle in an extraction process otherwise capable of concentrating useable THC from infinitesimal trace amounts found in the seed. Accordingly, "potential for abuse" provides no logical basis whatsoever for distinguishing animal feed mixture from, say, a multi-ingredient snack bar containing sterilized hemp seeds mixed with other ingredients that have even less trace THC by volume than animal feed.

C. DEA's Failure to Extend the Exemption to Edible Hemp Seed and Oil and Seed and Oil Products is Arbitrary and Capricious

To be sure, as DEA claims, the agency is not obligated to exempt any substances at all from the CSA under its section 811(g)(3) authority. "Congress gave DEA discretionary authority to issue such exemptions." Rule 206F, 68 *Fed. Reg*. at 14120, ER at 29. But having "established that [an agency] has broad authority to grant or deny exemptions," the court must still "consider whether [the agency] has exercised that authority in an arbitrary and capricious fashion." *Airmark Corp. v. Federal Aviation Administration*, 758 F.2d 685, 691 (D.C. Cir. 1985). "[A]n agency may not exercise its discretion in an arbitrary and capricious manner…." *Idaho Power Co. v. Federal Energy Regulatory Comm'n*, 766 F.2d 1348, 1351 (9th Cir. 1985).

As this Court has explained:

> A decision is arbitrary and capricious if the agency 'has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency or is so implausible that it could not be ascribed to a difference in view or product of agency expertise.

O'Keeffe's Inc. v. U.S. Consumer Prod. Safety Comm'n, 92 F.3d 940, 942 (9th Cir. 1996), *quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co*., 463 U.S. 29, 43 (1983).

It is well established that agency action is arbitrary and capricious, under this standard, when an agency treats like cases differently without adequate explanation. "Deference to agency authority or expertise…'is not a license to … treat like cases differently.'" *Airmark Corp., supra*, 758 F.2d at 691, *quoting United States v. Diapulse Corp*., 748 F.2d 56, 62 (2d Cir. 1984). "'A long line of precedent has established that an agency action is arbitrary when the agency offers insufficient reasons for treating similar situations differently.'" *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1022 (D.C. Cir. 1999), quoting *Transactive Corp. v. United States*, 91 F.3d 232 (D.C. Cir. 1996). For example, in *Natural Resources Defense Council v. U.S. Environmental Protection Agency*, 966 F.2d 1292 (9th Cir. 1992), the Court held that EPA's exemption of certain types of light industry from portions of the Clean Water Act was arbitrary and capricious because the agency's distinction between various types of industrial activities was based on an "unsubstantiated assumption" about the differences between pollution generated by the different types. 966 F.2d at 1305.

In this case, DEA's distinction between animal feed and other products containing hemp seed or oil is also completely unsupported. DEA has no express statutory authority to exempt animal feed. The agency has determined that it is appropriate to exempt animal feed anyway, because

Congress intended to exempt animal feed and because there is no real potential for abuse. Both propositions are equally true of edible hemp seed and oil products.[13] Yet DEA has utterly failed to explain why it has declined to exempt such products. Its failure to extend the exemption for animal feed to edible hemp seed and oil products, is a manifest, unexplained failure to treat similar cases in like fashion. The absence of such an exemption, therefore, is arbitrary and capricious.

III. DEA VIOLATED THE REGULATORY FLEXIBILITY ACT IN ISSUING RULE 205F

The Regulatory Flexibility Act, 5 U.S.C. §§601-11 ("RFA"), "requires a federal agency to prepare a regulatory flexibility analysis and an assessment of the economic impact of a proposed rule on small business entities, 5 U.S.C. §604, unless the agency certifies that the proposed rule will not have 'a significant economic impact on a substantial number of small entities,' and provides a factual basis for that certification, id. at §605…." *Environmental Defense Center, Inc. v. Natural Resources Defense Council, Inc*., 319 F.3d 398, 449 (9th Cir. 2003). "In granting relief under RFA §611,

[13] Although the primary existing U.S. hemp industry for seed at the time of Congress's exemption was for birdseed, Members of the congressional committees of jurisdiction nonetheless specifically inquired and were advised that human ingestion of hemp seed was not problematic in making the exemption for sterilized seed. *E.g*., Hearings on H.R. 6385, 75th Cong., 1st Sess. 61 (1937).

a court may order an agency to 'take corrective action consistent with' the RFA and APA, including remand to the agency,…." *Id*.

In this case, although DEA purported to certify that Rule 205F will not have a significant impact on a substantial number of small entities, under RFA section 605(b), DEA did in fact perform both an initial regulatory flexibility analysis, in the Proposed Rule, 66 *Fed. Reg*. at 51535-38, ER at 13-16, and in the final rule, Rule 205F, 68 *Fed. Reg*. at 14117-18, ER at 26-27. However, DEA failed to adequately address a crucial factor required by RFA section 604: "a description of the steps the agency has taken to minimize the significant economic impact on small entities…including a statement of the factual policy and legal reasons for selecting the alternative adopted in the final rule and why *each one* of the other significant alternatives to the rule considered by the agency…was rejected" (emphasis added).

DEA's analysis failed to account in any way, or even to acknowledge, that the proposed rule would destroy the manufacture of body care and cosmetic products in the U.S., using hemp oil imported from Canada and other foreign countries, since the importation of such oil, regardless of its intended use, would be banned by the rule.

More importantly, DEA failed to adequately analyze the most straightforward policy alternative to DEA's rulemaking; namely, for DEA to have considered hemp seed foods just like poppy seed foods, and not have issued the rules at issue in the first place, given that current regulations completely control for any potential form of cannabis or synthetic THC drug use.[14] FDA, as the government agency charged with maintaining food safety, is the proper agency to address trace insignificant THC in non-drug hemp seed and oil foods.[15] As noted above, any hypothetical instances of

[14] DEA's suggestion that it lacks authority to establish an "acceptable" level of "adding" THC to foods, Rule 205F, 68 *Fed. Reg.* at 14124, ER at 33, is inapposite. In the first place, 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 to 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 and nutrition bars. In the second place, FDA, not DEA, is the government agency charged with establishing tolerances for trace contaminants in the U.S. food supply.

[15] 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

hemp seed or oil foods that contain psychoactive quantities of "marihuana" resin are already controlled as "marihuana" under the CSA, as derivatives of the resin, just as any hypothetical poppy seed products with narcotic quantities of opium resin are controlled under the definition of "opium" in the CSA.

DEA's failure to perform a proper regulatory flexibility analysis was highlighted by the 2002 report of the Office of Advocacy of the U.S. Small Business Administration to the Office of Management and Budget; the Office of Advocacy is required by RFA section 612(a) to monitor agency compliance with the RFA. In this report, in addressing the Interpretive Rule, the Office of Advocacy noted that:

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fact, the hemp seed and oil in Petitioners' products generally contain undetectable THC in the seed and oil 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 alleviate 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. Rule 205F, 68 *Fed. Reg.* at 14124, ER at 33. 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 of the safety and nutritional value of these products.

> The problem is that DEA never did an analysis of impacts on the long-existing hemp foods industry—an industry comprised entirely of small businesses that would now have to remove all its products from the shelves and cease manufacturing and selling the products….DEA refused to consider establishing guidelines to allow products that did not leave detectable traces of THC in the bloodstream.

SBA Report at 8-9. The SBA report assesses the impact of the "Interpretive Rule" (which has the same legal effect as Rule 205F) as, "The entire hemp food industry would be eliminated." *Id*. at 9.

Even if Rule 205F were otherwise valid, then—and it clearly is not—the rule should be remanded to the agency for the undertaking of a proper regulatory flexibility analysis.

CONCLUSION

For the reasons set forth above, the Court should find that Rule 205F is invalid under the CSA and order that it be set aside.

If the Court finds that Rule 205F is valid, it should remand the rule to DEA to undertake a proper regulatory flexibility analysis; and should also find that DEA's failure to extend the exemption set forth in Rule 206F to edible hemp seed and oil products is arbitrary and capricious, and contrary to law.

STATEMENT OF RELATED CASES

Pursuant to Circuit Rule 28-2.6, there is pending in this Court a related case, *Hemp Indus. Ass'n, et al. v. Drug Enforcement Administration, et al.*, No. 01-71662. As described in the Statement of the Case, *infra*, No. 01-71662 is a Petition for Review of DEA's "Interpretive Rule," 66 *Fed. Reg. 5*1530 (Oct. 9, 2001), ER at 8. Petitioners are unaware of any related cases other than No. 01-71662.

Respectfully submitted,

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