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

REPLY BRIEF OF PETITIONERS

Patrick Goggin, SBN # 182218
590 Athens Street
San Francisco, CA 94112
Telephone/Fax: (415) 334-2117

Joseph E. Sandler (Admitted)
John Hardin Young
Sandler, Reiff & Young, P.C.
50 E Street, S.E.
Washington, D.C. 20003
Telephone: (202) 479-1111

Dated: August 11, 2003 Attorneys for Petitioners

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SUMMARY OF ARGUMENT

DEA Rule 205F purports to ban all forms of hemp stalk, fiber, seed and oil, notwithstanding that the Controlled Substances Act's definition of "Marihuana" specifically exempts those substances from control. Rule 206F then purports to "exempt" from that blanket ban those processed hemp products that are not hemp stalk, seed or oil raw materials, or that are not processed hemp seed or oil products intended for human consumption. Although DEA's argument conflates the two rules, they must be analyzed

separately. If there is no statutory authority for the blanket ban of Rule 205F in the first place, then there is no basis for DEA to exempt only certain substances from that ban.

The *Chevron* standard is not applicable to Rule 205F because DEA, in promulgating that rule, did not act pursuant to its delegated authority under the CSA. DEA is authorized to add substances to the CSA schedules only through the scheduling process specified in the statute, requiring that a formal rulemaking be conducted and that certain specific findings be made. It is undisputed that these procedures were not followed.

Even if *Chevron* were applicable, this Court's review should stop with step one of *Chevron* because the statute is clear and unambiguous: hemp stalk, fiber, seed and oil were not controlled prior to Rule 205F. The listing of "THC" refers only to synthetic THC and does not and cannot cover the trace miniscule amounts of organic THC in the resin of hemp seed. That "THC" includes any substance containing "any quantity" of THC does not provide any basis for reading the exemption of hemp stalk, fiber, seed and oil out of the statute. The listing of THC by its terms does not cover any substance "specifically excepted." And, contrary to DEA's contention, it is *not* possible that the parts of the cannabis plant excluded from the definition of "Marihuana" could fit within the listing of other controlled substances or

otherwise be subject to control under the Act, because such a reading would render the statutory exemption of hemp stalk, fiber, seed and oil utterly superfluous.

Were the Court to reach step two of *Chevron*, legislative history should be irrelevant. Congressional intent is clear from the face of the statute, and DEA's "interpretation", reading the statutory exemption of hemp stalk, fiber, seed and oil out of the statute, is simply not a "permissible construction." In any event, the legislative history of the statute only confirms that the trace amounts of THC contained in these exempted items are not covered by the listing of THC. Nor does the fact that the market for edible hemp products developed relatively recently bear on this Court's review, since the statute draws absolutely no distinction between edible forms of hemp seed and oil and any other forms. Because Rule 205F adds these substances to CSA Schedule I without DEA having followed the procedures for scheduling a new substance, Rule 205F is invalid.

Review of Rule 206F is a moot exercise since that rule merely purports to exempt from control certain processed hemp products that DEA has no authority to control in the first place. In any event, Rule 206F is itself arbitrary and capricious because there is no rational basis for distinguishing hemp seed used in animal feed, which Rule 206F exempts, from hemp seed

used for human consumption. The notion that Congress "had in mind" use of hemp seed for animal feed but not for human consumption is belied by the fact that the statute itself shows that Congress was aware of the trace amounts of THC in the resin of hemp seed but (i) believed those trace amounts were harmless and (ii) separately and specifically provided for control of any extract or concentrated form of the resin by providing that "Marihuana" would include "the resin extracted" from hemp seed, oil, fiber or stalk. And DEA has made no findings at all about any potential for abuse, other than the potential for extraction and concentration into a substance that is already controlled as "Marihuana."

For that same reason, it is absurd for DEA to suggest that respecting the plain Congressional intent would "open a loophole" for drug traffickers by permitting the extraction and concentration of resin from hemp seed. Any such "resin extracted" from hemp stalk, fiber, oil or seed is specifically controlled as "Marihuana." The loophole conjured up by DEA simply does not exist.

There is no reason why the clear intent of Congress should not be respected. Hemp stalk, fiber, seed and oil are not covered by the CSA. DEA's rule purports to add those substances. It failed to follow the

prescribed procedures for making such an addition. Its rule is therefore invalid.

ARGUMENT

I. INTRODUCTION

The controlling issue in this case is whether hemp stalk, fiber, seed and oil were already covered by Schedule I of the Controlled Substances Act ("CSA"), 21 U.S.C. §812(c), prior to issuance of DEA's new rule, DEA Rule 205F (21 C.F.R. §1308.11(d)(27), as added by 68 *Fed. Reg*. 14114 (March 21, 2003)(Excerpts of Record ("ER") at 23). If hemp stalk, fiber, seed and oil were *not* already covered, then it is clear that DEA's new rule (Rule 205F) purported to place those substances onto Schedule I, for the first time.

Congress has delegated to the Attorney General (who has delegated to DEA) the power effectively to amend the CSA, by adding new substances to a CSA Schedule, including Schedule I. 21 U.S.C. §811(a). But, not surprisingly, Congress has provided that this vast delegated legislative authority must be exercised in accordance with specified procedures and safeguards, specifically (i) that the scheduling action take the form of a formal rulemaking, *i.e*., on the record after opportunity for hearing, *id*. §811(a); (ii) that certain specific findings be made—in

particular, in the case of Schedule I, that the "drug or other substance has a high potential for abuse," *id*.§ 812(b)(1); (iii) that DEA must consider eight separate factors set out in 21 U.S.C. §811(c); and (iv) that DEA obtain a scientific and medical evaluation, and recommendations, with respect to certain of those factors, from the Department of Health and Human Services. *Id*. §811(b). It is undisputed that DEA failed to follow any of these procedures or make the required findings. For that reason Rule 205F is invalid.

DEA's answer is effectively to assume that hemp stalk, fiber, oil and seed are all *already* covered under Schedule I and then to defend the reasonableness of their decision to exempt certain processed hemp products to the extent those products are not hemp stalk, seed and oil from which potent drug preparations could allegedly be extracted or are not intended for human consumption. DEA bases that defense on the notion that Congress "really" meant to exempt hemp only for "industrial" use. The problem with DEA's argument is that the plain language of the statute does not cover hemp stalk, fiber, seed and oil in the first place, but rather expressly *exempts* all of them from the coverage of the statute. The statute itself exempts *all* of these substances. There is no occasion for DEA to decide to exempt only

some of them-- unless DEA has some statutory basis to control any of them, to begin with. And that statutory basis is precisely what DEA lacks.

DEA suggests, frighteningly, that giving effect to the plain language of the statute would "create a loophole in the law" because drug traffickers could use "raw cannabis material to produce an extract that could contain a substantial concentration of THC." (DEA Brief at 38-39). Nowhere does DEA address, however, or even acknowledge, the clear statutory language in the CSA definition of "Marihuana" that speaks directly and unambiguously to that issue—that hemp stalk, fiber, seed and oil are exempted, *"...(except for the resin extracted therefrom)."* 21 U.S.C. §802(16)(emphasis added). This phrase demonstrates that in creating this exemption, Congress was not only very much aware of the non-harmful trace resin content in the exempted portions of the cannabis plant that contain miniscule traces of the substance formally identified in the 1960's as THC, but also that Congress expressly controlled for the highly unlikely hypothetical possibility that this trace resin could be concentrated or extracted or otherwise made into an active drug preparation. Thus, the "extract" conjured up by DEA is already defined as "Marihuana." There is no "loophole" to be closed.

Indeed, DEA's rulemaking would be an entirely pointless exercise if all it purported to do was to place natural THC on Schedule I, without affecting the statutory exemption for hemp stalk, seed, oil and fiber. That is because any resin derivatives (such as hashish or hypothetical 100% natural THC refined from the resin) of both the exempted and non-exempted portions of the cannabis plant are *already* controlled as "Marihuana" as derivatives of the resin. What Rule 205 in fact does, instead, is attempt, by regulation, to eliminate the express statutory exemption for hemp stalk, seed, oil and fiber.[1]

II. RULE 205F IS A SCHEDULING ACTION BECAUSE HEMP STALK, FIBER, SEED AND OIL WERE NOT ALREADY COVERED BY SCHEDULE I OF THE CSA

A. DEA 205F and 206F Must Be Analyzed Separately for Purposes of Judicial Review

DEA argues that Rules 205F and 206F "must be read together" for purposes of review by this Court. (DEA Brief at 11). DEA's effort to

[1] Since the exempted portions of the cannabis plant are exempted only to the extent that the non-harmful trace resin is not concentrated or extracted or otherwise made into any active drug product capable of abuse, it would presumably be pointless for DEA to attempt to undertake a scheduling process for the purpose of attempting to place these non-drug substances onto any CSA schedule. By definition, the exempted portions of the cannabis plant contain only non-harmful trace resin content and thus are inherently incapable of abuse; as noted, to the extent that the resin is concentrated into an active drug product, such preparations are already controlled as derivatives of the resin.

conflate its two rules, however, begs the question of whether hemp stalk, fiber, seed and oil are already controlled to begin with. Rule 205F purports to bring under Schedule I *all* hemp stalk, fiber, seed and oil to the extent such substances have *any* THC "naturally contained…." in them. Rule 205F, amending 21 C.F.R. §1308.11(d). The threshold question, then, is whether DEA, in Rule 205F, properly placed on Schedule I all hemp stalk, fiber, seed and oil, since all such substances do contain non-psychoactive miniscule trace amounts of residual resin, which contain insignificant naturally-occurring THC.

If DEA did *not* properly place those substances on Schedule I via Rule 205F, then it is irrelevant whether the agency's decision to exempt processed non-edible forms of these substances (in Rule 206F) was "permissible" under *Chevron*. If none of these substances was already on Schedule I, and DEA did not conduct a proper scheduling action to put them there, then Rule 205F is invalid—and there is no occasion for DEA to go on to create any "exemptions" from Rule 205F, via Rule 206F. For this reason, the two rules must be analyzed separately.

B. The *Chevron* Standard Is Inapplicable to Rule 205F

DEA asserts that because Rule 205F was promulgated through notice-and comment rulemaking, it is entitled to *Chevron* deference. (DEA

Brief at 10). *Chevron* deference is due to an agency regulation or ruling only where such regulation or ruling is promulgated pursuant to "express congressional authorizations to engage in the process of rulemaking or adjudication…." *United States v. Mead*, 533 U.S. 218, 229 (2001). No *Chevron* deference is accorded to "an agency guideline where congressional delegation did not include the power to 'promulgate rules or regulations….'" *Id*., *citing EEOC v. Arabian American Oil Co*., 499 U.S. 244, 257 (1991). "[W]here it is in doubt that Congress actually intended to delegate particular interpretive authority to an agency, *Chevron* is 'inapplicable'". *Mead,* 533 U.S. at 230, *citing Christensen v. Harris County*, 529 U.S. 576, 596-97 (2000)(Breyer, J., dissenting).

In this case, Congress did not delegate to the DEA the legislative authority to amend or add to the CSA schedules through notice and comment rulemaking. Rather, that delegation was expressly conditioned on the use by DEA of formal rulemaking under APA sections 556 and 557: that is, the CSA explicitly requires that, "Rules…under this subsection shall be made on the record after opportunity for a hearing…." 21 U.S.C. §811(a). APA section 553(c) provides that, "When rules are required by statute to be made on the record after opportunity for agency hearing, sections 556 and 557 of this title apply….." 5 U.S.C. §553(c).

There is no dispute in this case that DEA failed to conduct a formal rulemaking on the record. It did not, therefore, act pursuant to the legislative authority delegated to it by Congress. For that reason, DEA's alteration of or addition to the CSA Schedules, through its new regulation, is not entitled to *Chevron* deference.

Indeed, had DEA conducted a proper scheduling action, including formal rulemaking on the record, its resulting rule would not be reviewed under the "arbitrary and capricious" standard including *Chevron* deference, but rather under the "substantial evidence" test of APA section 706(2)(E)("unsupported by substantial evidence in a case subject to sections 556 and 557 of this title…."). *See, e.g.*, *American Tunaboat Ass'n v Baldridge*, 738 F.2d 1013, 1015 (9th Cir. 1984)("A formal rule-making proceeding is reviewed under the APA's substantial evidence standard"). DEA makes no effort to defend its rule under that standard of review.

C. Even if *Chevron* Were Applicable, Review Should Stop With *Chevron* Step One Because the Statute Is Clear and Unambiguous

To the extent DEA is arguing that its new regulation banning all hemp substances (Rule 205F) is merely its "interpretation" of what is *already* contained in CSA Schedule I, and therefore that DEA is acting pursuant to general rulemaking authority of 21 U.S.C. §871(b) (*see* DEA

Brief at 13-14), *Chevron* might arguably be applicable. In that case, as DEA correctly points out, "*Chevron* step one is a pure question of statutory construction and does not involve an analysis of the legislative history or policy goals of the statute." (DEA Brief at 12). "'On a pure question of statutory construction, our first job is to try to determine congressional intent, using traditional tools of statutory construction.'" *Dole v. United Steelworkers of America*, 494 U.S. 26, 35 (1990), *quoting NLRB v. Food and Commercial Workers*, 484 U.S. 112, 123 (1987).

In this case, the language of the CSA definition of "Marihuana" explicitly provides that the term "does not include" hemp stalk, fiber, seed and oil. 21 U.S.C. §801(16). In the face of this express language, DEA contends that the text of schedule I(c)(17), referring to "THC," could reasonably be interpreted "to refer to both natural and synthetic THC," *i.e.*, the miniscule trace naturally-occurring THC in hemp stalk, fiber, seed, and oil, since the statute does not "forbid" such an interpretation and the "common meaning" of THC includes both natural and synthetic forms. (DEA Brief at 14-15). As this Court explained, however, in *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082 (9th Cir. 2003)(*Hemp I*), DEA's current and previous regulations limiting the listing of "THC" to synthetic THC—

> gave effect to the exemption for sterilized seeds under marijuana and, …recognized that the listing of THC in

> Schedule I did not cover the trace amounts of organic THC in the sterilized seeds.

333 F.3d at 1091. That Congress specifically exempted hemp stalk, fiber, seed and oil, but not the "resin extracted therefrom," makes clear that "THC" as listed in Schedule I in the statute does not and cannot include the miniscule trace amounts of naturally-occurring THC in those hemp elements. For that reason alone, DEA's "interpretation" defies the plain meaning of the statute, as a simple matter of statutory construction.

Further, as Petitioners noted, the listing in which THC appears in Schedule I, 21 U.S.C. §812(c), covers "any material, compound, mixture, or preparation, which contains any quantity of" a listed substance, "*Unless specifically excepted*…" (emphasis added). Any insignificant trace THC contained in hemp stalk, fiber, seed and oil, of course, is "specifically excepted" in the definition of "Marihuana" set forth in 21 U.S.C. §802(16). DEA claims this is a "strained reading" of the statute for three reasons.

First, DEA suggests that "excepted" refers only to DEA exemption by regulation under 21 U.S.C. §811(g), or to Congressional exemption elsewhere in the CSA. (DEA Brief at 16-17). Nothing in the language of the CSA in any way indicates that the term "specifically excepted" is limited to these two situations. In any event, in this case, "Congress itself has excepted a particular substance from control," (DEA

Brief at 17): it has specifically excepted hemp stalk, seed, fiber and oil in section 802(16) of the same Act.

Second, DEA contends that, since the definition section of the CSA applies to all sections of the Act, there would be no reason to say, "unless specifically excepted," in one of the Schedules, in order to refer to the definitions. Those words however—"Unless specifically excepted … any material, compound, mixture," etc.-- on their face clearly encompass exceptions found elsewhere in the Act, including the definitions—for example, the definition of "controlled substance," excluding distilled spirits and tobacco, found in 21 U.S.C. §802(6), another subsection of the definitions' section (cited by DEA itself, Brief at 18).

Third, DEA insists that the separate listings of "Marihuana" and "THC" mean that it is possible that the parts of the cannabis plant excluded from the definition of "Marihuana" could "fit within the listing of other controlled substances or otherwise be subject to control under the Act." (DEA Brief at 18). Such a reading of the Act, however, simply makes no sense, as a matter of straight statutory construction. 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). As this Court explained in *Hemp I*, DEA's reading "would be specious, as it …would nullify the explicit exemption of hemp seed and oil from the coverage of marijuana."[2] 333 F.3d at 1090.

DEA insists that Rules 205F and 206F "do not render superfluous the part of the definition of marijuana that excludes" hemp stalk, fiber, seed and oil, because this "part of the definition is given significant effect through the exemptions in DEA-206F…." (DEA Brief at 19). The question, however, is whether the *statutory* definition of "THC" covers hemp stalk, fiber, seed and oil in the first place. If so, then the *statutory* exemption of hemp stalk, fiber, seed and oil, in the statutory definition of "Marihuana", would be rendered a nullity, as this Court recognized in *Hemp I*. That problem cannot be cured through regulatory exemptions (Rule 206F) of *some* hemp stalk, fiber, oil and seed from a statute (21 U.S.C. §802(16)) that exempts *all* of them.

[2] DEA suggests that there are other substances controlled in their natural, as well as synthetic, form, even though the plant from which they are derived is separately listed. (DEA Brief at 35-36). That is simply not true of THC, which as listed, refers only to synthetic THC. *Hemp I,* 333 F.3d at 1091. In any event, none of the other substances identified by DEA is derived from a plant of which specified portions are specifically exempted from control notwithstanding that they contain miniscule non-active natural trace amounts of the drug component.

For these reasons, even if *Chevron* was applicable to Rule 205F, the review should stop at step one, because "If the intent of Congress is clear, that is end of the matter…." *Chevron USA Inc. v. Natural Resources Defense Council, Inc*., 467 U.S. 837, 843 (1984). "'The traditional deference courts pay to agency interpretation is not to be applied to alter the clearly expressed intent of Congress.'" *Microsoft Corp. v. Comm'r of Internal Revenue*, 311 F.3d 1178 (9th Cir. 2002), *quoting Bd. Of Governors of Federal Reserve System v. Dimension Finance Corp*., 474 U.S. 361, 368 (1986). In this case, the intent of Congress has been made crystal clear by the plain language of the CSA: hemp stalk, fiber, seed and oil are not presently controlled as THC, notwithstanding that they contain insignificant trace amounts of naturally-occurring resin/THC.

D. Legislative History Is Immaterial to Review of Rule 205F

As its analysis under step two of *Chevron*, DEA attempts to use the legislative history of the Marihuana Tax Act of 1937 to justify Rules 205F and 206F, by showing that the two new rules, in combination, "allow for everything Congress had in mind" (DEA Brief at 26) by exempting non-edible processed hemp products but not hemp stalk, seed and oil raw materials from which potent drug preparations could allegedly be extracted, or processed hemp seed and oil products intended for human consumption.

(*Id*. at 22-27.) Again, however, DEA's analysis ignores the fact that Rule 205F bans *all* hemp stalk, fiber, seed and oil on the basis that those substances are already included on CSA Schedule I as "THC." If DEA is wrong on that score, and Rule 205F is therefore invalid, the validity of Rule 206F is moot: there is no need to review a rule purporting to create exemptions to another rule that is invalid.

As noted, review of Rule 205F itself should stop with *Chevron* step one. Even if the Court were to proceed to step two, however, the question is whether the agency's regulation is "based on a permissible construction of the statute," DEA Brief at 22, *citing Chevron*, 467 U.S. at 843. Here, as discussed above, the plain language of the CSA makes clear that hemp stalk, fiber, seed and oil are not controlled, notwithstanding trace amounts of THC. See section II(c), *infra*; *Hemp I*, 333 F.3d at 1091. For that reason alone, DEA's construction of the statute is not "permissible."

In these circumstances, DEA's reliance on legislative history is misplaced. "[R]eference to legislative history is inappropriate when the text of the statue is unambiguous." *Dept. of Housing & Urban Development v. Rucker*, 535 U.S. 125, 132 (2002); *see United States v. Hockings,* 129 F.2d 1069, 1071 (9th Cir. 1997)(court resorts to legislative history only "[i]f the

statute is unclear").[3] In any event, as to Rule 205F, as this Court noted, "The DEA cites nothing in the legislative history of the act to show that the 1970 Congress consciously intended to cover naturally-occurring THC under THC as well as under marijuana." *Hemp I*, 333 F.3d at 1089.[4] Thus, even if this Court were to proceed to step two of *Chevron*, DEA's reading of the hemp exclusion out of the statute is simply not a "permissible construction."

E. Rule 205F Is an Invalid Attempted Scheduling Action

1. Lack of a Long Historic Use of Hemp Foods Does Not Support a Finding that Any Hemp Stalk, Fiber, Seed or Oil Have Ever Been Covered by the CSA

Ultimately, DEA readily concedes that "it has been the general practice of DEA in the past to treat sterilized cannabis seeds as noncontrolled even if they contain trace amounts of THC due to resin or leaves." (DEA Brief at 32). Yet DEA still insists that Rule 205F, controlling such seeds for the first time, is not a scheduling action because in

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[3] Petitioners' discussion of legislative history in their opening brief was only in connection with review of Rule 206F, *not* Rule 205F. Petitioners' Opening Brief at 35-39. As discussed below, legislative history is indeed relevant to review of Rule 206F, if there is any need to reach review of that rule.

[4] It is also unclear why DEA is placing such reliance on the history of the 1937 Act, given its position that "such legislative history cannot be deemed indicative of the intent of Congress under the CSA." DEA Brief at 23; *see also id.* at 26 ("the intent of Congress under the 1937 Act is not controlling in construing the CSA").

treating hemp seeds as "noncontrolled," DEA only had in mind bird seed; the market for hemp foods did not develop until relatively recently (*id*. at 32, 36-37); and thus:

> Up until that time, the question of human consumption of cannabis seeds was a nonissue for DEA. Once the agency became aware that cannabis seeds were being used for human consumption in the late 1990's, it assessed the situation and determined that it was legally permissible and sound policy to interpret the CSA to prohibit the human consumption of such seeds if they contain THC.

(*Id*. at 32).

The lack of long historic use of edible hemp seed and oil, and oil and seed products,[5] cannot possibly bear on the key question of whether Rule 205F is a scheduling action. Is DEA actually suggesting that hemp seed, containing trace THC, has always been on Schedule I, but that DEA simply looked the other way for 30 years, declining to enforce the law, as long as the seed was used for animal feed? Either hemp stalk, fiber, seed and oil containing miniscule trace amounts of THC were on Schedule I,

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[5] DEA misstates the facts regarding the development of a market for edible hemp seed and oil and oil and seed products in the U.S. As explained in the Declaration of Candi Penn, attached as Exhibit 1 to Reply of Petitioners in Support of Urgent Motion for Stay Pending Review (filed April 14, 2003, in this docket), edible hemp seed and oil products were introduced into the U.S beginning in 1989; the market has been rapidly growing ever since; and, in 2002 alone, imports just of hemp oil into the U.S. for food and cosmetic products totaled 228,400 kilograms with an entered value of $1,964,775. (U.S. International Trade Comm'n, USITC Database, HTS 1515.90.90.10.)

since the law was enacted in 1970, or they were not. If they were, then bird seed was also unlawful, notwithstanding DEA's "practice" of treating such seed as noncontrolled. If they were not, then Rule 205F is *adding* them to the CSA schedules and is a scheduling action.

The statute itself absolutely draws no distinction between hemp seed and oil used for human consumption and hemp seed and oil used for other purposes. Thus it is nonsensical for DEA to suggest that "THC-containing cannabis food products had no established exemption status under the CSA prior to the issuance of the rules [Rules 205F and 206F]…." (DEA Brief at 37). Hemp seed and oil used for human consumption had the same status under the CSA as all other hemp seed and oil, until issuance of Rule 205F. The status was that they were noncontrolled.

In this regard, the status of hemp seed is exactly like that of poppy seeds. As Petitioners have noted, poppy seeds are exempted by statute, 21 U.S.C. §802(19), yet poppy seed bagels are literally a "compound, mixture, or preparation which contains any quantity" of opiates. 21 U.S.C. §§802(17)(A) & 802(17)(F).[6] DEA protests that the "exemption

[6] Although DEA continues to insist that THC is treated differently than opiates by virtue of the CSA's use of the language "any quantity", as noted, the definition of "narcotic drug" uses precisely the same language with respect to opiates.

in federal law for poppy seeds has always been for the specific and sole purpose of using the seeds in food," whereas "the use of cannabis seeds in foods developed only well after the enactment of the CSA." (DEA Brief at 43-44). But the CSA statutory exemption for poppy seed, like that for hemp seed, is a blanket exemption: in neither case does the statutory language make any reference whatsoever to food use or non-food use. And there would be no more reason for Congress to be concerned about trace non-harmful miniscule amounts of THC in the trace resin of hemp seed than about such trace amounts of opiates in connection with poppy seeds.[7]

Thus, the real reason for DEA's "practice" of treating hemp seed as being noncontrolled has nothing to do with bird seed. The real reason is that it is indeed noncontrolled, as a matter of law. As this Court explained, DEA's "practice," reflected in its longstanding regulation, simply "gave effect to the exemption for sterilized seeds under marijuana and, reading the plain language of its regulation, recognized that the listing of THC in Schedule I did not cover the trace amounts of organic THC in the sterilized seeds." *Hemp I*, 333 F.3d at 1091.

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[7] Indeed, in the cases both of poppy seed and hemp seed, the seed is exempted from the CSA under the applicable definition for the controlled plant, but only to the extent the respective residual resins are not extracted or concentrated in any way into an active drug substance.

2. Because Hemp Stalk, Fiber, Seed and Oil Are Not Currently Controlled, Rule 205F Is an Invalid Attempted Scheduling Action

As DEA explained, "section 811 [requiring a scheduling procedure] applies only where DEA seeks to *add* a substance to a schedule….." (DEA Brief at 34, quoting Rule 205F, 68 *Fed. Reg*. at 16116, ER at 25). Precisely because hemp stalk, fiber, seed and oil are not currently controlled either as "Marihuana" or "THC," the effect of Rule 205F is clearly to *add* those substances to CSA Schedule I. Rule 205F thus clearly represents a scheduling action under 21 U.S.C. §811(a), undertaken without the required formal rulemaking or required findings.

In response, DEA contends again that no scheduling procedure is needed because the THC contained in hemp stalk, fiber, seed and oil is already controlled. Thus, DEA posits, if "grapefruit juice hypothetically were found to contain THC," the listing of "THC" would "automatically make it a controlled substance" and "DEA would not have to engage in the formal scheduling procedures… in order to 'add' such a substance to schedule I." (DEA Brief at 38). That is not so, however. If somehow, someday grapefruit juice were found to contain naturally-occurring THC, DEA would indeed be required to engage in a formal scheduling procedure, to put the relevant plant, parts and/or extracts of the grapefruit, or its juice,

on a CSA Schedule. That is because grapefruits are not currently covered in any CSA Schedule and neither is the imaginary naturally-occurring THC in grapefruit. DEA might, in this hypothetical example, find some potential for abuse of a concentrated extract of such a grapefruit.

Of course, in reality, as DEA notes, "grapefruit juice does not contain THC; nor are there any known plant materials other than those derived from the cannabis plant that naturally contain THC." (DEA Brief at 38). The only forms of natural THC that raise any potential for abuse are *already* scheduled as "Marihuana," specifically including any substance extracted or concentrated from the resin of hemp stalk, fiber, seed or oil (the "resin extracted therefrom…."). That is precisely why DEA does not pretend that there would be any point in following the proper scheduling procedure to schedule hemp stalk, fiber, seed or oil. Instead, DEA has attempted to ban those plant portions *without* a scheduling procedure. That it cannot do. Accordingly, Rule 205F is invalid.

III. DEA HAS FAILED TO JUSTIFY RULE 206F'S TREATMENT OF LIKE SITUATIONS DIFFERENTLY

As discussed above, there is no reason for this Court to review Rule 206F, since Rule 205F is invalid. If this Court did find it necessary to undertake such a review, however, it should find that Rule 206F is arbitrary and capricious because it treats like situations—hemp seed used for animal

feed and other products containing hemp seed and oil, used for human consumption—differently, without an adequate explanation.

This is not a question of statutory construction and, accordingly, the *Chevron* two-step analysis is inapplicable. The guiding principle is that "'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).

DEA acknowledges that it has no authority under 21 U.S.C. §811(g)(3) to exempt animal feed but not hemp used for other purposes. (DEA Brief at 21; Rule 206F, 68 *Fed. Reg*. at 14119-20, ER at 28-29). Accordingly, DEA is relying on its general rulemaking authority under 21 U.S.C. §871(b). *Id*. Exercising that authority, DEA observed that "the legislative history of the 1937 Marihuana Tax Act reveals that Congress expressly contemplated allowing 'hemp' animal feed." Rule 206F, 68 *Fed. Reg.* at 14121, ER at 30. In its brief, DEA relies on legislative history indicating that "Congress heard testimony" about various industrial uses of cannabis, but not any use for human consumption. As Petitioners demonstrated in their opening brief, however, Congress also heard testimony

about use of seed and oil for human consumption. Hearings on H.R. 6385, 7th Cong. 1st Sess. 52-54, 61 (1937). DEA simply dismisses that testimony cited by Petitioners as a "passing reference".

Even if Congress did not specifically focus on use of hemp seed and oil for human consumption in 1937, however, it is clear from the legislative history that Congress was aware "that hemp seed and oil contain small amounts of the active ingredient in marijuana, but that the active ingredient was not present in sufficient proportion to be harmful." *Hemp I*, 333 F.3d at 1089. That much is clear from the language of the statute itself, exempting hemp seed and oil but specifically controlling "the resin extracted therefrom." 21 U.S.C. §802(16). For this reason, the legislative history does not justify exempting animal feed but not edible hemp seed and oil. In other words, the legislative history does *not* show that Congress believed that the infinitesimal trace amounts of "active ingredient" were harmful but that it would not matter as long as the ingredient was just consumed by animals. To the contrary, the legislative history shows Congress understood that the miniscule trace amount of "active ingredient" was *not* sufficient to be harmful, period. It makes no sense, then, to assume that Congress believed the insignificant trace amount of "ingredient" present in hemp seed and oil was safe for animals but not for humans.

To this DEA replies that "due to improvements in technology, there have been significant advances since 1937 in the scientific understanding about THC…." (DEA Brief at 28). Yet DEA itself pointed out, in its "Interpretive Rule," that it was "[i]in the late 1960's when synthetic THC began showing up in the illicit market…." Congress was thus aware of THC (not merely an unidentified "ingredient") by 1970 and indeed covered synthetic THC in the CSA of 1970. Yet Congress did not revisit or modify the exemption for hemp stalk, fiber, seed and oil—even though it is clear that Congress was aware of insignificant trace amounts contained in the resin of those plant parts as early as 1937.

In any event, DEA itself suggests, in Rule 206F, that the legislative history is not a sufficient justification for exempting hemp seed used for animal feed but not other hemp seed and oil: "The historical lack of federal regulation of some THC-containing products….does not—by itself—justify exempting such products from control under the CSA." Rule 206F, 68 *Fed. Reg*. at 14121, ER at 30. Rather, DEA relies principally on the proposition that the "presence of a controlled substance in animal feed poses less potential for abuse than in a product intended for human use." *Id*.

Yet DEA has made no findings whatsoever, in Rule 205F or 206F, about any potential for abuse of any edible hemp seed or oil products

containing infinitesimal trace amounts of naturally occurring THC. Nor does DEA's brief identify any such findings. And again, to the extent DEA is supposedly concerned about efforts to concentrate the miniscule resin content of hemp seed into an active drug substance, the hemp seeds in an animal feed mixture would be as susceptible to such an effort as the hemp seeds contained in a multi-ingredient snack bar.

Indeed, the cover note attached to the Office of National Drug Control Policy's (ONDCP's) March 28, 2000 "Discussion Paper" (attached as Exhibit 6 to Petitioners' Reply to Respondents' Memorandum in Opposition to Petitioners' Emergency Motion for Stay, in *Hemp I*, (filed Feb. 22, 2002)), suggests that DEA's concern with hemp substances arises from factors *other* than a potential for abuse. ONDCP asserts that the Department of Justice should change its legal position regarding its lack of statutory authority to control hemp seed and oil because (i) hemp seed and oil "threatens the viability of our Federal drug testing system"; and (ii) the hemp industry generally serves as a "stalking horse" for marijuana legalization. In fact, the former is simply not true, and the latter makes as much sense as poppy seed bagels being a "stalking horse" for opium legalization.

The two justifications offered by DEA for its differential treatment of animal feed and hemp seed and oil used for human consumption—legislative history and potential for abuse-- are simply unsupported. For that reason, Rule 206F, to the extent it fails to exempt hemp seed and oil used for human consumption, is arbitrary and invalid.

IV. ENFORCING THE REQUIREMENTS OF THE CSA WILL NOT OPEN A "LOOPHOLE" IN THE DRUG LAWS

In arguing that the statute should be read as if it already covers hemp stalk, fiber, seed and oil, DEA holds out the frightening specter that respecting the plain language of the law "would provide a loophole in the law that might be exploited by drug traffickers." (DEA Brief at 38). DEA argues that if hemp stalk, seed and oil were actually recognized as noncontrolled (as the statute plainly says), "anyone could obtain this raw cannabis plant material to produce an extract that could contain a substantial concentration of THC." (*Id*. at 39).

This argument is utterly meritless—not merely because creating such an extract is technically and economically unfeasible, but for an entirely different reason: as noted above, if such an extract *were* ever created, it would *already* be controlled as "Marihuana," under Schedule I. That is because such an extract would, by definition, be "the resin extracted therefrom," *i.e*., the resin extracted from hemp stalk, oil or seed, which resin

is expressly controlled as "Marihuana" and has been since 1937. 2 U.S.C. §802(16). In other words, the act of extracting and concentrating the resin from exempt hemp stalk, oil or seed *already* brings such an extract back under the definition of "Marihuana."

Indeed, there is absolutely no form of cannabis that is capable of abuse that is not already controlled under the CSA. The definition of "Marihuana" covers not only the parts of the plant with a drug effect but also all derivatives of the resin from <u>*both*</u> non-exempted portions of the plant (flowers and leaves) and exempted portions of the plant (stalk, seed, fiber and oil), including hashish as well as hypothetical 100% natural THC. And the listing of "THC" covers any and all forms of synthetic THC.

Thus, the "loophole" for drug traffickers conjured up by DEA simply does not exist. Congress well understood what it was doing. It provided for an airtight statutory scheme for control of those forms of the cannabis plant capable of any abuse.

The "loophole" bogeyman thrown up by DEA is in fact a straw man. It does not and cannot excuse DEA from complying with the requirements of the law it has been entrusted to enforce. Because DEA failed to comply with those requirements, its new rule, Rule 205F, is invalid.

V. DEA PERFORMED A REGULATORY FLEXIBILITY ANALYSIS BUT DID SO IMPROPERLY

DEA's reliance on its own certification, under 5 U.S.C. §605(b), that the rule would not have a significant impact on small businesses, is misplaced. DEA effectively conceded the invalidity of that certification by actually performing a regulatory flexibility analysis which, as Petitioners noted, was deficient in two principal respects:

(1) It failed to take into account the impact on U.S. manufacturers of personal care and cosmetic products. While DEA blithely asserts that such a manufacturer could obtain a registration and permit to import hemp seed oil for use in manufacturing such products, it is unclear that anything in DEA's regulations entitle the manufacturer to such a permit or registration.

(2) The analysis also failed to analyze any policy alternative to Rule 205F, in particular, the obvious alternative of treating hemp seed foods just like poppy seed foods and not issuing the new rule to begin with.

For these reasons, the regulatory flexibility analysis in fact performed by DEA was deficient.

CONCLUSION

For the reasons set forth above, and in Petitioners' opening brief, the Court should find that Rule 205F is invalid under the CSA and order that the rule be set aside. If the Court finds that Rule 205F is valid, it should find that DEA's failure to extend the exemption set forth in Rule 206F to edible hemp seed and oil products is arbitrary, capricious and contrary to law.

Respectfully submitted,

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Patrick Goggin SBN #182218
590 Athens Street
San Francisco, CA 94112
Telephone/Fax: (415) 334-2117

Joseph E. Sandler (Admitted to Bar of this Court)
John Hardin Young
Sandler, Reiff & Young, P.C.
50 E Street, S.E.
Washington, D.C. 20003
Telephone: (202) 479-1111
Fax: (202) 479-1115