June 1, 2016

Via Hand-Delivery

Honorable Chuck Rosenberg, Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Re: Petition for Removal of Industrial Hemp Plants from Schedules Established Under the Controlled Substances Act

Dear Administrator Rosenberg:

Pursuant to 21 C.F.R. §1308.43, the Hemp Industries Association ("HIA") and the Kentucky Hemp Industry Council hereby petition the Drug Enforcement Administration to initiate proceedings for issuance of a rule, pursuant to section 201 of the Controlled Substances Act (the “CSA”), 21 U.S.C. §811(a), to remove entirely from the Schedules established under the CSA, industrial hemp plants as defined by section 7606 of the Agricultural Act of 2014, P.L. 133-79, namely, Cannabis sativa L. plants with a THC concentration of not more than three-tenths of one percent on a dry weight basis.

Set forth below are (i) the proposed rule in the form proposed by the petitioners; and (ii) a statement of the grounds upon which the petitioners rely for the issuance of the rule.

In summary, in 2000, the DEA rejected a petition filed in 1998 for a rule that would remove from the Schedules cannabis plants containing one percent or less of delta-9-tetrahydrocannabinols ("THC"), when cultivated by persons licensed by the U.S. Department of Agriculture. The agency rejected that petition on two main grounds: first, that petitioner was proposing a “hypothetical” substance defined by an “arbitrary percentage of a controlled substance” contained in the plant; and second, that the CSA does not distinguish plants based on the percentage of controlled substances contained in them.

Two key developments occurring since the year 2000 render those grounds no longer valid. First, in 2004, the U.S. Court of Appeals for the Ninth Circuit ruled that the naturally-occurring THC in cannabis plants is not itself a controlled substance under the CSA. Thus, the industrial hemp plant is not a plant that “contains” a controlled substance; rather it is a controlled substance solely by virtue of being the same species as the drug marijuana plant (Cannabis sativa L.). Second, Congress itself has now, in the Agricultural Act of 2014 (the “2014 Farm Bill”), specifically defined and identified industrial hemp as a plant different from other, drug marijuana Cannabis plants.
As set forth in detail below, the manufacture and sale of hemp products in the United States is now a half a billion dollar a year industry. Twenty-nine States have enacted laws either authorizing the commercial cultivation of industrial hemp under a state regulatory regime and/or providing for cultivation for pilot programs and research purposes by the State departments of agriculture or colleges and universities, as authorized by the 2014 Farm Bill. DEA has the authority, and under the circumstances, the obligation, to reconsider the status of industrial hemp under the CSA Schedules. The current state of scientific research and years of experience with industrial hemp in the U.S. and other countries make it clear that industrial hemp plants do not meet the requirements for inclusion in any Schedule established under the CSA. The reasons for prior rejection are no longer valid. Accordingly, this Petition should be granted.

I. Proposed Rule

21 C.F.R. §1308.11(d) (23) is amended to read as follows:

“(23) Marihuana, except for industrial hemp as defined in 7 U.S.C. §5940(b)(2)
........ 7360.”

II. Grounds for Issuance of the Proposed Rule

A. Background

1. Nature and Uses of Industrial Hemp

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. Congressional Research Service, Hemp as an Agricultural Commodity (July 24, 2013) (“CRS Rpt.”) Industrial hemp plants grown in Canada and Europe are bred to contain less than three-tenths of one percent (0.3%) by weight of THC (the psychoactive element) in the upper portion of the flowering plant, respectively, while marijuana varieties average about 10% THC, and range upward to much higher levels. Id. at 2. Since a level of 1% THC “is considered the threshold for cannabis to have a psychotropic effect or an intoxicating potential,” flowers from industrial hemp have no potential for drug use. Id.

Industrial hemp “can be grown as a fiber, seed or dual purpose crop.” Id. at 4. Hemp fiber is valued for its length, strength and durability. Id. at 4; E. Small & D. Marcus, Hemp: A New Crop with New Uses for North America in J. Janick & A. Whipkey (eds.), TRENDS IN NEW CROPS AND NEW USES 284-326 (2002)(reprinted at https://www.hort.purdue.edu/newcrop/ncnu02/v5-284.html (last visited May 14, 2016; page references herein are to online version); see also U.S. Department of Agriculture, Economic Research Service, Industrial Hemp in the United States: Status & Market Potential (Jan. 2000). Hemp fiber derived from hemp stalk is used by U.S. companies in the manufacture of textiles and fabrics, yarns and spun fibers, and for paper, carpeting, home furnishings, construction and insulation materials, auto parts and composites. CRS Rpt. at 5; see Small & Marcus at 10-17. There are an estimated 5 million vehicles in North America today that contain interior panels molded from hemp fiber bio-
composite material. Johnson Controls, FlexForm Technologies, and Composites America are three US companies that use hemp fiber in this way.

Hemp hurds derived from the stalk are also issued in animal bedding, material, inputs, papermaking and composites. CRS Rpt. at 5.

Hemp seeds are also used in the U.S. directly as a nutritious food ingredient and also crushed for hemp seed oil and seed cake. “Hemp is of high nutritional quality because it contains high amounts of unsaturated fatty acids, ...” Small & Marcus at 21. Hemp seed oil is used in a variety of food and beverages. CRS Rpt. at 5. The seed contains 20% high-quality digestible protein and is also an excellent source of essential fatty acids. There is a growing U.S. market for hemp milk, which is a popular substitute for soy milk and similar products. Food products made in the U.S. containing hemp ingredients include roasted and hulled seed, nutrition bars, tortilla chips, pretzels and beer. Small & Marcus at 21.

Oil from crushed hemp seed 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. CRS Rpt. at 5.

It has been estimated that “the global market for hemp consists of more than 25,000 products in nine submarkets: agriculture; textiles; recycling; automotive; furniture; food/nutrition/dietary supplement; paper; construction materials; and personal care.” Id. at 4.

Although pilot hemp cultivation projects have commenced in the U.S. as discussed below, companies currently selling hemp seed and oil food, nutritional and personal care products in the U.S. generally either import hemp seed and oil from Canada, China or Europe, for use in manufacturing these products in the U.S., or import already finished products from Canada or Europe. CRS Rpt. at 6-7. “Approximately 30 countries in Europe, Asia and North and South America currently permit farmers to grow hemp.” Id. at 9.

The HIA has estimated that, in 2015, total retail sales of hemp products in the U.S. totaled $573 million, with hemp foods constituting $90 million; personal care products accounting for $147 million; textiles and clothing products for $95 million; dietary supplements for $47 million; hemp derived Canadian products, for $65 million; industrial applications including building materials and car parts, for $116 million; and other consumer products such as paper construction materials, for the remainder. Hemp Industries Association, “2015 Annual Retail Sales for Hemp Products Estimated at $573 Million,” May 9, 2016, located at www.thehia.org/HIAhemppressreleases/4010402 (last visited May 12, 2016). Hemp products are currently sold at thousands of US retailers including well-known companies such as Whole Foods Market, Target, Costco and Walgreens among others.
2. **Current Legal Status of Industrial Hemp**

(a) **Controlled Substances Act**

The hemp plant—although useless as drug marijuana—is the same species as the marijuana plant, Cannabis Sativa L. The express language of the Controlled Substances Act ("CSA"), however, provides that hemp stalk, fiber, oil and sterilized seed are not controlled as marijuana. The definition of "Marihuana" specifically excludes "the mature stalks of such [cannabis] 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..." 21 U.S.C. §802(16) (emphasis added). Thus, an express exclusion of hemp stalk, fiber, oil and sterilized seed was adopted by Congress more than 75 years ago in order to make clear that its intention was only to regulate drug-cannabis and that it did not intend to interfere with the legitimate hemp industry.

The UN Single Convention Treaty on Narcotic Drugs of 1961 to which the United States is a signatory, specifically states in Article 28 regarding Control of Cannabis that cultivation of cannabis for industrial purposes is not restricted:

This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.

In 2004, the U.S. Court of Appeals for the Ninth Circuit invalidated U.S. Drug Enforcement Administration regulations which would have banned the manufacture and sale of edible products made from hemp seed and oil. *Hemp Industries Ass’n v. Drug Enforcement Administration*, 357 F.3d 1012 (9th Cir. 2004). The Court affirmed that non-psychoactive hemp products do not contain any controlled substance as defined by the CSA and that "[t]he non-psychoactive hemp in Appellants' [edible and personal care] products . . . fits within the plainly stated exception to the CSA definition of marijuana. Congress knew what it was doing and its intent to exclude non-psychoactive hemp from regulation is entirely clear." *Id.* at 1018.

Because the industrial hemp plant is the same species as marijuana, until recently, it has been illegal for U.S. farmers to grow the plant itself; the plant thus remains a controlled substance under the CSA. While unrestricted commercial cultivation of the industrial hemp plant is illegal under U.S. federal law, as noted, it is legal in more than 30 countries. CRS Rpt. at 9. Hemp farming has been legal in Canada for almost 20 years. Global hemp production has increased overall from about 250 million pounds in 1999 to in excess of 380 million pounds in 2011. *Id.* So U.S. companies must import hemp, stalk, fiber, seed and oil from China, Canada and, to some extent, Europe and elsewhere in Asia, instead of purchasing it from U.S. farmers.

This situation has created a lost opportunity for U.S. agriculture. Hemp is a sustainable, fast growing, high-yielding and mechanically strong plant. As noted, the U.S. market for industrial hemp stalk and fiber, while less developed than that in Europe and China, is still very substantial and would provide U.S. industrial hemp farmers significant opportunities—opportunities now lost to them. *See CRS Rpt.* at 7-9.
(b) **2014 Farm Bill**

In the federal Agricultural Act of 2014, P.L. No. 113-79 (commonly known as the “2014 Farm Bill”), Congress specifically, and for the first time since enactment of the CSA, exempted from the CSA cultivation of industrial hemp under agricultural pilot programs authorized by state law. Section 7606 of the 2014 Farm Bill, 7 U.S.C. §5940, provides, in pertinent part, that:

(a) In General—Notwithstanding the Controlled Substances Act (21 U.S.C. 80 et seq.), the Safe and Drug-Free Schools and Communities Act 920 U.S.C. 7101 et seq.) chapter 81 of title 41, United States Code, or any other Federal law, an institution of higher education…of a State department of agriculture may grow or cultivate industrial hemp if

(1) The industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and

(2) The growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education or State department of agriculture is located and such research occurs.

Section 7606 specifically defines “industrial hemp” to mean “the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” 7 U.S.C. §5940(b)(2).

Section 7606 defines “agricultural pilot program” to mean a program to study the growth, cultivation or marketing of industrial hemp—

(A) in States that permit the growth or cultivation of industrial hemp under the laws of the State; and

(B) in a manner that—

(i) ensures that only institutions of higher education and State department of agriculture are used to grow or cultivate industrial hemp;

(ii) requires that sites used for growing or cultivating industrial hemp in a State be certified by, and registered with, the State department of agriculture; and

(iii) authorizes State departments of agriculture to promulgate regulations to carry out the pilot programs in the States in accordance with the purposes of this section.

Reinforcing Congressional recognition of industrial hemp as a legitimate agricultural crop distinct from drug marijuana, at the end of last year Congress enacted, as part of the Consolidated Appropriations Act, 2016, P.L. 114-113, a provision mandating that:

None of the funds made available by this Act or any other Act may be used:

(1) in contravention of the section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940); or
(2) to prohibit the transportation, processing, sale or use of industrial hemp that is grown or cultivated in accordance with section 7606 of the agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated.


(c) State Laws

At least twenty-two States have enacted legislation authorizing the cultivation of industrial hemp under state law in some way and under various conditions. Of these, thirteen states have enacted laws legalizing the full commercial cultivation of industrial hemp in the state, subject to state licensing requirements and, in a few states, conditional on the legality of such cultivation under federal law. These thirteen states are California, Cal. Food & Ag. Code §§81000 et seq.; Colorado, Col. RSA §§35-61-101 et seq.; Indiana, Indiana code §§ 15-15-13-1 et seq.; Kentucky, KRS §§260.850 et seq.; Maine, 7 Maine R.S.A. §2231; Maryland, Agriculture Art. §14-101; Minnesota, MSA §§18K.01 et seq.; Montana, Mont. Code Ann. §§8018-101 et seq.; North Dakota, N.D. Cent. Code §§4-41-01 et seq.; Oregon, ORS §§571.300 et seq.; South Carolina, S.C. Code Ann. §§46-55-10 et seq.; Vermont, 6 VSA §§561 et seq.; and West Virginia, W. Va. Code §§19-12e-1 et seq.

Another nine states have enacted legislation providing for cultivation of hemp only for research purposes in agricultural pilot programs, by the State Department of Agriculture and institutions of higher education, as permitted by section 7606 of the 2014 Farm Bill. Those nine states include Delaware, Del. Code Ann. Tit. 3, ch. 28 §§2800 et seq.; Hawaii, S.B. 2175; Illinois, 720 IL CS 550/15.2; Michigan, MCLA §§286.841 et seq.; Nebraska, Neb. Rev. Stat. §2-5701; Nevada, NRS §§557.020 et seq.; York, McKinney’s Ag. & Markets Law §§505 et seq.; North Carolina, N.C. Stat. §§105-558.50 et seq.; Utah, Utah Code Ann. §§4-41-101 et seq.

Every one of these twenty-two state laws distinguishes industrial hemp plants from other Cannabis sativa L. plants on the basis of THC content by dry weight, following the lead of Congress (and international standards) in defining industrial hemp to be the Cannabis sativa L. plant with a THC concentration of not more than three-tenths of one percent on a dry weight basis.

B. DEA’s Grounds for Denying the Prior Petition to Remove Industrial Hemp from the Schedules Are No Longer Valid

On March 23, 1998, a number of companies and trade groups submitted a joint petition to the DEA and the U.S. Department of Agriculture, for issuance of rules that would remove from the Schedules cannabis plants containing one percent or less of THC, if and to the extent such plant was cultivated pursuant to a license issued by USDA. On December 19, 2000, the Administrator denied the petition and declined to initiate rule making proceedings, on three grounds. A copy of the denial is attached hereto as Exhibit 1 (“Denial Letter”). None of those grounds are currently relevant or valid.
(1) **No Other Agency Would Be Delegated Authority Under the CSA**

First, the Administrator concluded that the proposal would improperly delegate to the USDA the exclusive authority of DEA to authorize the manufacture and possession of a substance subject to the CSA. Denial Letter at 1-3. The Petitioners herein are not proposing that any other agency exercise any jurisdiction over any substance that is a controlled substance under the CSA.

(2) **Industrial Hemp Is Not a “Hypothetical” Substance Determined by the Presence of Any Controlled Substance**

The Administrator next contended that “creating a hypothetical substance by selecting an arbitrary percentage of a controlled substance in a plant does not warrant a scientific and medical evaluation for the purpose of scheduling.” Denial Letter at 3. The Administrator reasoned that Congress did not intend to allow petitioners “to trigger scientific and medical scheduling evaluations by DEA and the Department of Health and Human Services (HHS) simply by imagining hypothetical formulations of substances containing relatively low percentages of controlled substances.” Denial Letter at 4. Indeed, the Administrator explained, such an exercise could lead to an endless series of scheduling actions as petitioners submitted petitions asking for de-scheduling of cannabis plants with successively lower percentages of THC. *Id.* at 4-5.

This contention is no longer valid for several significant reasons. First, the identification of industrial hemp as a plant distinct from drug marijuana can no longer be characterized as the “creation of a hypothetical substance.” The definition of industrial hemp as a cannabis plant containing three tenths of a percent or less by weight of THC (far less than the standard proposed in the 1998 petition) is internationally recognized. “Current laws regulating hemp cultivation in the European Union (EU) and Canada use 0.3% THC as the dividing line between industrial and potentially drug-producing cannabis.” CRS Report at 2. That definition has now been explicitly adopted by the Congress in the 2014 Farm Bill. 7 U.S.C. §5940. And that definition has been uniformly adopted in the laws of more than twenty States, as cited above in section II(A)(2) of this Petition. There is nothing at all “hypothetical” about industrial hemp as a plant distinct from drug marijuana.

In that regard, the Administrator also inaccurately suggested in the Denial Letter that that no one “can predict with certainty—prior to planting—the percentage of THC that will be contained in a cannabis plant.” Denial Letter at 5 n.3. To the contrary, industrial hemp and marijuana can be, and are routinely, deliberately bred to contain completely different levels of THC—trace amounts in the CSA of hemp and significant concentrations in the CSA of drug marijuana. “[M]odern, commercial hemp and marijuana cultivars were intensely selected for different characteristics including the opposite extremes of cannabinoid content.” S.L. Datwyler and G.D. Weiblen, *Genetic Variation in Hemp and Marijuana (Cannabis sativa L.) According to Amplified Fragment Length Polymorphisms*, 51 J. FORENSIC SCIENCES 371, 374 (2006). “[H]emp is genetically different and is distinguished by its use and chemical makeup, as well as by differing cultivation practices in its production.” CRS Rpt. at 1.
Second, the Administrator’s characterization of industrial hemp as a plant “containing” a specified percentage of a “controlled substance” is no longer legally tenable. In Hemp Indus. Ass’n v. DEA, 357 F.3d 1012 (9th Cir. 2004), the HIA challenged DEA’s final rules relating to hemp products, one of which would have amended the listing of THC in Schedule I to include natural as well as synthetic THC. DEA, Clarification of Listing of THC in Schedule I, 68 Fed. Reg. 14114 (March 21, 2003). Companion final rules would have exempted from control non-psychoactive hemp products containing trace amounts of THC only if such products were not intended to enter the human body.

The Court ruled that the definition of THC under the CSA includes only synthetic THC—and that naturally-occurring THC in cannabis plants is not itself a controlled substance and therefore that the otherwise-exempted parts of the cannabis plant—hemp stalk fiber, and sterilized seed—are not subject to control despite containing trace amounts of naturally-occurring THC. The Court ruled that DEA’s treatment of naturally occurring trace amounts of THC in hemp products “improperly renders naturally occurring non-psychoactive hemp illegal for the first time.” 357 F.3d at 1017. The Court reasoned that:

Congress was aware of the presence of trace amounts of psychoactive agents (later identified as THC) in the resin of non-psychoactive hemp when it passed the 1937 “Marihuana Tax Act,” and when it adopted the Tax Act marijuana definition in the CSA. . . . Congress knew what it was doing, and its intent to exclude non-psychoactive hemp from regulation is entirely clear. Id. at 1018.

This ruling makes clear that industrial hemp plants are not controlled because they contain a “controlled substance,” i.e., naturally occurring THC, since such THC is not, in itself, a controlled substance. Rather, industrial hemp plants are controlled solely because they are of the same species as drug marijuana.

Thus, distinguishing industrial hemp plants from other Cannabis sativa L. plants is not a matter of determining the extent to which plants contain a controlled substance. It is a matter of determining whether the industrial hemp plant as a recognized distinct plant, meets the criteria for being retained on any of the Schedules established under the CSA. That question was not addressed at all in the Denial Letter. It is addressed in section II(C) of this Petition, below.

(3) De-scheduling Does Not Involve Distinguishing Plants Based on the Percentage of Controlled Substances Contained Therein

In his Denial Letter, the Administrator’s final contention was that there “are many provisions of the CSA that apply expressly to plants that are the source of controlled substances. In none of these provisions did Congress make any distinctions based on the percentage of controlled substance contain in (or potentially derived from) the plant.” Denial Letter at 5.

Again, in view of the development of the law since issuance of the Denial Letter, it is clear that the Administrator’s position is wrong as a matter of law. Cannabis sativa L. is
controlled as a specific species. It is not controlled because it contains any controlled substances; to the contrary, the THC naturally occurring in that plant is not itself a controlled substance under the CSA, as the Court made clear in HIA v. DEA II, supra.

The correct question is not whether a plant can be distinguished based on the amount of a controlled substance contained in the plant. The question is whether industrial hemp, as a recognized distinct sub-category of this plant, is easily distinguishable from other Cannabis plants, thereby meeting the statutory criteria for being removed from the Schedules. That issue is addressed below.

C. Industrial Hemp Meets the Statutory Criteria for Being Removed From the CSA Schedules

DEA may by rule remove any substance from the schedules if it “finds that the…substance does not meet the requirements for inclusion in any schedule.” 21 U.S.C. §811(a). To be included on any of the five Schedules, a substance must have some potential for abuse. 21 U.S.C. §812(b).

The industrial hemp plant, with a THC concentration of three tenths of a percent or less by dry weight, has no potential for abuse whatsoever. First, ingestion of industrial hemp, whether by smoking, eating or otherwise, will not cause any psychoactive effect at all, as has been established by studies going back over many years. A 1988 study showed that smoking cannabis with a 0.9% THC concentration produced primarily placebo-appropriate discrimination responding, i.e., no psychoactive effects attributable to a drug. LD Chait et al, Discriminative stimulus and subjective effects of smoked marijuana in humans, 94 PSYCHOPHARMACOLOGY (Berl) 206 (1988). A review ten years later, of the studies conducted to that point, concluded that “the threshold concentration for the discrimination of smoking marijuana from smoking placebo seems to be somewhere in the order of 0.8-1.0% THC,” and that:

[It]seems reasonable and useful to classify Cannabis into three distinct categories: drug types (>1% THC), whose products are used recreationally and medicinally; inter-mediate types (.0.3-1.0% THC) with only a small drug potential, depending on the CBD/THC ratio; and fiber types (industrial hemp, fiber hemp) (<0.3% THC) use for the production of fiber and seeds with no drug potential.


In their 2002 review of the scientific literature, Small & Marcus concluded that:

A THC concentration in marijuana of approximately 0.9% has been suggested as a practical minimal level to achieve the (illegal) intoxicant effect, but CBD (the predominant cannabinoid of fiber and oilseed varieties) antagonizes (i.e. reduces) the effects of THC…Concentration of 0.3% to 0.9% are considered to have ‘only a small drug potential’…
Small & Marcus at 7 (citation omitted). They further conclude that:

As noted above, a level of about 1% THC is considered the threshold for marijuana to have intoxicating potential, so the 0.3% level is conservative and some countries... have permitted the cultivation of cultivars with higher levels. [A] level of 0.3% THC in the flowering parts of the plant is reflective of material that is too low in intoxicant potential to actually be used practically for illicit production of marijuana or other types of cannabis drugs.

*Id.* at 8. For these reasons, “[c]urrent laws regulating hemp cultivation in the European Union and Canada use 0.3% THC as the dividing line between industrial and potentially drug producing cannabis.” CRS Rpt. at 2.

Second, ingestion of industrial hemp does not cause false positives in drug testing for drug marijuana. A widely-recognized 2001 controlled study concluded that daily ingestion of up to 0.6 mg of THC did not produce confirmed positive urine THC results; and that ingestion even of these amounts of hemp oil and seed containing 5/10 of one percent and 2 tenths of 1 percent “requires ingestion of unrealistic amounts of such products.” G. Leson, F. Grotenhermen, H. Kalant & M ElSohly, *Evaluating the Impact of Hemp Food Consumption on Workplace Drug Tests*, 25 JOURNAL OF ANALYTICAL TOXICOLOGY 691, 697 (2001). Other studies have confirmed these results. [cite]

Third, cultivation of industrial hemp does not present the risk that farmers cultivating industrial hemp will mix drug marijuana plant with their crop, thereby creating the risk of diversion and complication of drug marijuana enforcement efforts. As the CRS Report explains:

Because of the compositional differences between the drug and fiber varieties of cannabis, farmers growing either crop would necessarily want to separate production of the different varieties or cultivars. This is particularly true for growers of medicinal or recreational marijuana in an effort to avoid cross-pollination with industrial hemp, which would significantly lower the THC content and thus degrade the value of the marijuana crop. Likewise, growers of industrial hemp would seek to avoid cross-pollination with marijuana plants, especially given the illegal status of marijuana.

CRS Rpt at 2-3. Even more significantly, pollen from male hemp plants will cause female marijuana flowers to go to seed, rendering such marijuana almost worthless. Industrial hemp and drug marijuana are also harvested at different times (*id.* at 3) and there are marked visual differences as well: hemp is grown tall whereas marijuana “is selected to grow short and tightly clustered;” hemp is “grown as a single main stalk with few leaves and branches, whereas marijuana is encouraged to become bushy with many leaves and branches to promote flowers and buds;” and “hemp is densely panted to discourage branching and flowering whereas marijuana plants are well-spaced.” *Id.* at 3.
Thus, industrial hemp has no potential for abuse whatsoever and, accordingly, there is no basis for retaining industrial hemp on any of the Schedules established under the CSA. This conclusion is confirmed by application of the eight factors set forth in 21 U.S.C. §811(b):

(1) Actual or relative potential for abuse. As explained above, industrial hemp has no actual or relative potential for abuse whatsoever.

(2) Scientific evidence of its pharmacological effect if known. The studies and literature reviews cited above indicate that it is impossible as a practical matter for a human being to ingest a sufficient amount of industrial hemp seed or oil to produce any psychoactive effect. There are no reliable studies at all that establish that industrial hemp (at the now well-established three tenths of one percent THC concentration level or lower) have ever produced any psychoactive effects in a human being.

(3) State of scientific knowledge. See discussion under (2) above.

(4) History and current pattern of abuse. While industrial hemp is currently being cultivated in the U.S. only in small quantities for research purposes under the Farm Bill, about 30 nations in Europe, Asia and North and South America currently permit farmers to cultivate industrial hemp. CRS Rpt. at 9. Global production of hemp in 2011 was more than 380 million pounds. Id. at 10. No nation has reported any problem or issue with abuse of industrial hemp as a drug, or any problem with enforcing laws against cultivation of drug marijuana.

(5) Scope, duration and significance of abuse. Again, as industrial hemp has no actual or relative potential for abuse, it is not, and never has been, abused. This factor clearly weighs in favor of removal of industrial hemp from the Schedules.

(6) What, if any, risk there is to the public health. As discussed above, cultivation of industrial hemp in the U.S. poses no risk of abuse, no risk of diversion of drug marijuana and no risk of interference with drug testing for employment, law enforcement or other purposes. Industrial hemp is only beneficial to public health and the environment.

(7) Psychic or psychological dependence liability. Industrial hemp, again as defined in the 2014 Farm Bill, has no potential psychoactive effect and, accordingly, no potential to create dependency of any kind, whether physical or psychological.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter. Industrial hemp is not a precursor to any controlled substance. As noted above, the THC contained in trace amounts in industrial hemp is not itself a controlled substance. Industrial hemp plants cannot be processed into or used as drug marijuana plants in any way.

CONCLUSION

For the reasons set forth above, this Petition should be granted and the DEA should initiate proceedings to adopt the proposed Rule.
Respectfully submitted,

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EXHIBIT 1
Mr. Jay Halfon  
P.O. Box 19405  
Washington, D.C. 20036

Dear Mr. Halfon:

This responds to your petition, dated March 23, 1998, asking the Drug Enforcement Administration (DEA) to initiate rule making proceedings pursuant to the Controlled Substances Act (CSA). Specifically, you petitioned DEA to propose a rule, pursuant to 21 U.S.C. § 811(a), that would amend the schedules of controlled substances such that cannabis plants containing one percent or less tetrahydrocannabinols (THC) would be removed entirely from CSA control when cultivated for "industrial hemp" by persons licensed by the United States Department of Agriculture (USDA). For the following reasons, your petition is hereby denied.

I. Your Proposed Rule Would Improperly Delegate CSA Regulatory Authority

The result of your proposed rule would be as follows. The USDA would issue licenses to persons to cultivate cannabis for industrial purposes. Persons so licensed would be permitted to grow cannabis containing up to one percent THC entirely outside of the system of controls established by the CSA. Neither DEA nor any other agency within the Department of Justice would have any role in the oversight of such production of cannabis. Such a fundamental change in the statutory scheme of the CSA cannot be reconciled with the intent of Congress.

Registration is the cornerstone of the CSA. This is reflected in the structure of the Act. Congress declared a blanket prohibition on all manufacturing, distributing, and dispensing of controlled substances, "[e]xcept as authorized by
[the Act]." 21 U.S.C. § 841(a)(1). To be authorized to engage in such activities, one must be registered with the Attorney General. As stated in 21 U.S.C. § 822(a)(2): "Every person who manufactures, distributes, or dispenses any controlled substance . . . shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by [her]." No one may manufacture, distribute, or dispense any controlled substance except to the extent they are authorized to do so by their registration. 21 U.S.C. §§ 822(b), 841(a)(1). Stated alternatively, the CSA uses the concept of "registration" to distinguish between authorized acts and unauthorized acts with respect to controlled substances. United States v. Moore, 423 U.S. 122 (1975) ("only the lawful acts of registrants are exempted") (italics added). Those who manufacture, distribute, or dispense controlled substances without the appropriate registration violate the CSA and are subject to criminal penalties. United States v. Blanton, 730 F.2d 1425 (11th Cir. 1984).

Thus, the agency that issues registrations is the agency that designates who may, and who may not, lawfully manufacture and distribute controlled substances. It is therefore crucial to bear in mind that Congress assigned to the Department of Justice (specifically to the Attorney General) the function of issuing registrations. As stated in the House Report to the CSA:

Title II: Control and Enforcement.—The bill provides for control by the Department of Justice of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal.


The above statement from the House Report makes clear that Congress directed that the Department of Justice serve as the licensing body for legitimate handlers of controlled substances. Your proposed rule would remove the Department of Justice entirely from the licensing and regulation of those who manufacture cannabis for industrial purposes and allow the USDA to take over this function. Such a proposal is not permissible under the CSA.
The Attorney General may not delegate any of her functions under the CSA to anyone other than an officer or employee of the Department of Justice. 21 U.S.C. § 871(a). Moreover, since issuance of registrations is such a critical function under the CSA, it would be particularly incongruous with the statutory scheme established by Congress to delegate this particular function to an agency outside the Department of Justice. On this basis alone, your petition must be denied.

Although no further analysis is required, we note below additional considerations that render your proposed rule incompatible with the CSA.

II. Your Proposal To Divide Cannabis Plants Into Different Scheduling Categories Based On An Arbitrary, Hypothetical Percentage Of THC Is Contradictory To The CSA

Under your proposed rule, cannabis plants would not be classified in a single CSA schedule. Rather, cannabis plants containing more than one percent THC would remain in Schedule I, while cannabis plants containing one percent or less THC would be removed entirely from the schedules (decontrolled) with respect to persons who have a USDA license to grow the plant for industrial purposes. Treating plants that are the source of controlled substances in this manner is contrary to the CSA in the following respects.

A. Creating a Hypothetical Substance by Selecting an Arbitrary Percentage of a Controlled Substance in a Plant Does Not warrant a Scientific and Medical Evaluation for the Purpose of Scheduling

The CSA scheduling criteria are not meant to be applied to hypothetical controlled substances. For example, one could not initiate CSA scheduling by petitioning DEA as follows:

I would like to market granola bars that contain one nanogram (one billionth of a gram) of lysergic acid diethylamide (LSD) per two-ounce bar. In my view, this concentration of LSD is so low that no one could eat enough of the granola bars to get any noticeable hallucinogenic effect. At the same time, I believe a

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1 Pursuant to 21 U.S.C. § 871(a), functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 28 C.F.R. § 0.100.
substantial number of persons would be interested in buying granola bars that are advertised as containing LSD. Therefore, please initiate proceedings to remove from the schedules (decontrol) LSD when contained in this granola bar formulation.

Although it is conceivable that a two-ounce granola bar containing one nanogram of LSD might have little or no potential for abuse, it certainly would not comport with the CSA to entertain the foregoing petition to decontrol LSD in such a formulation. Congress never intended to allow members of the public to trigger scientific and medical scheduling evaluations by DEA and the Department of Health and Human Services (HHS)\(^2\) simply by imagining hypothetical formulations of substances containing relatively low percentages of controlled substances.

In contrast, the scheduling procedures established by Congress were intended to be applied to new formulations of controlled substances where a company is seeking to market a new drug. Congress recognized that, in order to gain approval from the Food and Drug Administration to market a new drug, a company will undertake clinical studies to evaluate the safety and efficacy of the drug. As opposed to the hypothetical controlled substance whose formulation exists only in theory, an actual drug can be administered to research subjects with precise formulation in order to obtain scientific results. In this way, there will be a meaningful body of evidence for DEA (and HHS, where appropriate) to consider when it comes time to determine the appropriate schedule of such drug.

It is also worth noting that Congress neither intended nor equipped DEA or HHS to undertake, on their own, the clinical studies that would be required if they had to make scheduling determinations each time a member of the public invented a hypothetical controlled substance formulation and petitioned DEA for a scheduling action.

When it comes to plants, there is yet another reason why scheduling proceedings cannot be triggered by a member of the public picking an arbitrary percentage of a controlled substance in a particular plant and asking DEA to reschedule only those plants that contain precisely that percentage (or less) of the

\(^2\) The Attorney General must request from the Secretary of HHS a scientific and medical evaluation before initiating rulemaking proceedings to reschedule a controlled substances. 21 U.S.C. § 811(b).
controlled substance. If such a method of initiating scheduling proceedings were valid, then anyone could force DEA and HHS to engage in a potentially unending series of scheduling evaluations. This could occur in the following manner:

As you have done, a petitioner could ask DEA to decontrol cannabis plants containing a specific percent of THC (e.g., one percent). DEA would then, under your proposed scenario, refer the petition to HHS for a scientific and medical evaluation in accordance with 21 U.S.C. § 811(b) and (c). If, based on this evaluation, DEA concluded that a cannabis plant with one percent THC does have a "high potential for abuse" commensurate with Schedule I, and, therefore, denied the petition, the petitioner would be free (under your proposed scenario) to submit another petition. This subsequent petition would ask DEA and HHS to undertake the same analysis with respect to cannabis plants containing an arbitrary percentage of THC slightly lower than one percent. This process could go on endlessly with the petitioner continually reducing the percentage of THC in the hypothetical cannabis plant after each time DEA undertakes the medical and scientific analysis and denies the petition. It is unimaginable that Congress intended to allow the CSA rescheduling provisions to be used in this manner.

B. Various Provisions of the CSA Do Not Distinguish Plants Based on the Percentages of Controlled Substances Contained Therein

There are many provisions of the CSA that apply expressly to plants that are the source of controlled substances. In none of these provisions did Congress make any distinctions based on the percentage of controlled substance contained in (or potentially derived from) the plant. For example:

Congress declared as contraband (subject to seizure, summary forfeiture, and destruction) "all species of plants from which controlled substances in Schedules I and II may be derived" that are grown in violation of the CSA. 21 U.S.C. § 881(g). Under this provision, the entire illegally-grown plant is to be seized and destroyed. Congress did not entitle the grower to the return of any

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3 You do not assert in your petition (nor is there a basis to claim) that anyone can predict with certainty -- prior to planting -- the percentage of THC that will be contained in a cannabis plant. Likewise, you do not assert (nor is there is basis to claim) that cannabis seeds from a cannabis plant containing a certain percentage of THC will necessarily produce plants of equal or less THC concentration. Although these considerations are not bases upon which your petition is hereby denied, they cast further doubt on the viability of your proposed rule.
portions of such plant -- not even those portions that might arguably contain no significant amount of controlled substances.

Congress authorized the Attorney General to "conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted." 21 U.S.C. § 873(a)(5). This is noteworthy because many cannabis plants growing in the wild contain relatively low percentages of THC.

Congress provided that the penalties for unlawful cultivation of cannabis are based on the number of plants -- without regard to the percentage of THC in the plants. 21 U.S.C. § 841(b)(1)(A)(vii), (B)(vii), (D).

The foregoing provisions indicate that the percentage of a controlled substance in a plant is not a relevant factor for purposes of CSA control.

III. Notwithstanding Prior Legislation (The Marihuana Tax Act of 1937), The CSA Registration Requirement Does Apply To The Cultivation Of Cannabis For Industrial Purposes

In your proposed rule, you assert that, in view of the Marihuana Tax Act of 1937, having the USDA (rather than the Attorney General) license persons to grow cannabis for industrial purposes more accurately reflects the intent of Congress under the CSA. This assertion is mistaken, as the United States Court of Appeals for the First Circuit recently explained.

In New Hampshire Hemp Council, Inc. v. Marshall, 203 F.3d 1 (1st Cir. 2000), cert. denied 121 S. Ct. 77 (2000), the plaintiffs sued DEA, asking the court to declare that they be permitted to grow cannabis for industrial purposes without obtaining a DEA registration. The plaintiffs argued that Congress (in enacting the CSA) had not made it illegal to grow "low-THC" cannabis for industrial purposes. The First Circuit rejected this interpretation of the CSA and held that all persons who wish to cultivate cannabis for industrial purposes must obtain a DEA registration, regardless of the THC content of the cannabis plants.

Similar to your petition, the plaintiffs in New Hampshire Hemp Council pointed to the 1937 Marihuana Tax Act (which was repealed and superseded by the CSA in 1970) and the definition of marijuana therein. Plaintiffs in New Hampshire Hemp Council argued that the 1937 Act was meant to accommodate persons who wished to cultivate cannabis for
industrial purposes and that the CSA should be interpreted in the same way because the CSA adopted the definition of marijuana from the 1937 Act. The Court of Appeals explained how this argument is flawed:

Congress' main vehicle for protecting industrial-use plant production in 1937 was not its basic definition of "marijuana," which included plants ultimately destined for industrial use; it was the complex scheme of differential tax rates and other requirements for transfers. That is the regime that was drastically modified in 1970 in favor of a broad criminal ban (subject only to federal licensing), a ban which read literally embraces production of cannabis plants regardless of use.

The possibility remains that Congress would not have adopted the 1970 statute in its present form if it had been aware of the effect on cultivation of plants for industrial uses. But that is only a possibility and not a basis for reading the new statute contrary to its literal language, at least absent a clear indication that Congress intended to protect plant production for industrial use as it existed under the prior tax statute. Nor, given Congress' enlargement of drug crimes and penalties in recent years, would one bank on its adoption of an exception strongly opposed by the DEA as a threatened loophole in the ban on illegal drugs.

Id. at 7 (footnote and citation omitted).

For the foregoing reasons, your petition cannot be granted under the CSA and is, therefore, denied.

Sincerely,

Julio F. Mercado
Deputy Administrator