CURIO WELLNESS

Curio Wellness Comments on Food and Drug Administration's Request for Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds
Docket No. FDA-2019-N-1482
Hearing Date: May 31, 2019

THE CASE FOR SAFE AFFORDABLE MEDICINAL CANNABIS IN THE US
De-Scheduling Cannabis is the Safe Route to Normalization

I. EXECUTIVE SUMMARY

Over the past several years, the Federal government has deliberated modifying the current regulation of the Cannabis sativa L. plant and derivative compounds (collectively, "Cannabis") as Schedule I controlled substances, which effectively bans use of these products for any purpose. In response to formal inquiries by multiple US Senators and Governors, the U.S. Drug Enforcement Administration ("DEA") announced on August 11, 2016 that Cannabis does not meet the criteria for removal from Schedule I. However, this finding is in stark contrast to the scientific data which supports the removal of Cannabis from Schedule I. Even if Cannabis is taken out of Schedule I, the question will remain whether and how Cannabis and Cannabis-containing products (collectively, "Cannabis products") should be regulated. Controlled substances are regulated by DEA; however, assuming that Cannabis is de-scheduled, as it should be, an appropriate consumer product regulatory regime should be in place to enable consumer access, while ensuring safe and consistent manufacturing and distribution of products. With specific updates, the framework of the Federal Food, Drug, and Cosmetic Act ("FD&C Act" or "the Act") can be readily adapted for these purposes.

The States and Federal government must address both modern scientific knowledge and the political realities surrounding Cannabis products. It is time for Congress to de-schedule Cannabis completely, and to establish an evidence-based regulatory paradigm that acknowledges: (1) Cannabis products are useful and in demand; (2) one size does not fit all products from a regulatory perspective; and (3) American consumers are very capable to choose whether individual products may be right for them. Moving Cannabis from Schedule I to Schedule II is not appropriate or adequate, nor will it address the current legal conflict between Federal and State law. Instead, Congress should create an appropriate legal regime that incorporates the following elements:

1. **Assign public health standards for Cannabis products that will align with existing standards and regimes for other consumer products.** Although Cannabis should be taken off from any Controlled Substances Act ("CSA") schedule, it should not be de-regulated. Rather, Congress and the Federal government can readily adapt the FD&C Act and the well-established agency regimes that govern drugs, foods, and dietary supplements to provide appropriate safety, efficacy, labeling, and quality requirements for *Cannabis* products that make disease, structure/function, or health claims. The intended use and claims will define the classification for each product. (Targeted statutory revision would be necessary to clarify the FDCA's

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applicability. See Sections II & III) FDA **needs to provide guidance related to residual solvents, such as benzene, a known carcinogen in *Cannabis* extracts, since zero-solvent (super-critical CO_2) extraction processes are widely available**. FDA needs to be able to inspect facilities, and apply current Good Manufacturing Practices (cGMPs) to facilities operating to supply *Cannabis* and *Cannabis*-derived products to the U.S. The current state-by-state patchwork of regulations and standards is not consistent with FDA's long history of public safety.

2. **Affirm the role of individual States to register or license the outlets through which Cannabis products may be sold in or into their jurisdictions.** The proposed Cannabis regulatory approach will provide consistent Federal standards for product manufacturing and labeling but must still allow individual States to determine which outlets may sell to consumers.

3. **De-schedule Cannabis products so that they will no longer be regulated as controlled substances.** The collected scientific and medical evidence shows that Cannabis products have legitimate uses (including medical and consumer product uses) and do not present measurable risks of diversion and dependence that might properly subject products to continued regulation by DEA. Shifting Cannabis from Schedule I to Schedule II will not solve the problem. Rather, like similar products, Cannabis should be de-scheduled altogether (as it was prior to 1970), recognizing both scientific realities and State actions to date.

   As much as this is pertinent to oral and inhaled cannabis products, it is even more so when considering topical products used to supplement the endocannabinoid system and relieve inflammation. These topical creams, salves and ointments are impossible to abuse since they have no psychoactive properties, and ***cannot*** be abused by ingestion, injection or inhalation. These products have localized action and are not systemically absorbed. Lumping these products with other highly addicting and abusable drugs, such as are listed in Schedule I, have no scientific justification.

   Since *Cannabis* and *Cannabis*-derivatives were classified as Schedule I products, they were lawfully restricted from prior marketing under the dietary supplement rubric. Congress must tailor the time restriction for prior marketing to address this unique scenario. **This exception Is warranted because of the truly unique history of CBD and *Cannabis*-derived products, and thus we recommend that this exception be likewise unique to CBD and *Cannabis*.** (See Section II, below)

II. CANNABIS PRODUCTS SHOULD BE APPROPRIATELY REGULATED THROUGH THE FEDERAL FOOD, DRUG, & COSMETIC ACT

Cannabis products are being developed for a variety of different consumer purposes. These products are not all the same, and – like other botanical products – individual products should be regulated according to their intended uses and corresponding public health standards. The FD&C Act already provides a regulatory regime that has been adaptable over time to address a wide range of consumer products. With a few targeted modifications, that regime that can be easily adapted to apply appropriate standards to the range of *Cannabis* products that may be developed for present or future use.

More specifically, the Act currently enables the marketing of plant-derived compounds for different intended uses, ranging from those developed to treat disease ("drug" products such as Taxol (paclitaxel); derived from the Pacific Yew tree) to treat cancer and Fulyzaq (crofelemer; derived from the red sap of the Croton lechleri plant) to treat diarrhea in adults

with HIV/AIDS); those developed to provide nutrition, aroma, or taste ("food" products such as garlic and herbs); and those to support healthy bodily function ("dietary supplement" products such as Garlique capsules, rosehip powder to support cardiovascular health, or Echinacea to support immune function). *Cannabis* products can, and do, fit within these various categories. Again, one regulatory classification does not fit all:

A. **Some *Cannabis* products are intended to treat medical conditions. These products should be regulated as "drugs" by FDA.** For example, GW Pharmaceuticals recently developed a product, (Epidiolex®), containing CBD for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Such a product falls squarely within the FD&C Act's definition of a "drug" (i.e., "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" (21 U.S.C. § 321(g)), and GW Pharmaceuticals and the Agency have, in fact, applied that established pathway. There have been other synthetic products (Dronabinol®, Marinol®, Syndros®) reviewed and approved by FDA over the past dozen years with varying doses of THC for the conditions of chemotherapy-induced nausea and vomiting, and anorexia. Another product containing both cannabidiol and Delta-9 tetrahydrocannabinol, (Sativex®) was tested and approved for cancer pain.

   "Drug" products in the U.S. are generally subject to premarketing review and approval requirements, based on laboratory and animal studies, clinical trials in humans (including patients), and other evaluations. Data must demonstrate that a proposed drug product is both safe and effective for the intended use, and that quality standards (such as potency and purity levels) can be consistently achieved. Promotional claims must align with FDA-approved product labeling. If the circumstances warrant it, FDA may restrict drug products to prescription (Rx only) status due to potential toxicity of a product as it is intended to be used, or due to the inability of a patient to self-evaluate and treat a condition without professional oversight. If self-care is feasible, drug products may be approved for over-the-counter ("OTC") access.

   Cannabis products bearing drug claims are similarly situated to other plant-derived medications. Claims to treat epilepsy, multiple sclerosis, or other specific diseases appropriately are considered "drugs" within the context of the existing regulatory regime.

B. **Some *Cannabis* products are intended for use as food.** For example, industry may wish to position *Cannabis* as food ingredients (*e.g.*, in baked products, or used to prepare herbal tea). Such a product should be presumptively a "food" (i.e., articles used for food or drink for man or other animals (21 U.S.C. § 321(f)) and subject to the safety requirements, health and nutritional claim regulations, and substantiation requirements that apply to food products), as long as disease claims are not made about the product.

   Ingredients intended for food use must satisfy long-established FDA requirements for authorization. Some may be "generally recognized as safe" by qualified experts for their intended use; others must be affirmatively approved by FDA as "food additives" (a data-driven process that evaluates the composition and properties of a substance; the amount that typically would be consumed; immediate and long-term health effects; and

various safety factors). Food ingredient evaluations consider appropriate levels of use, including built-in safety margins. In addition to compositional requirements, formulated food products are subject to requirements related to labeling disclosures, the types of health-related claims and nutrient content claims they may bear, and requirements for substantiation of claims. Manufacturers must apply good manufacturing practice ("GMP") in both food ingredient and finished product production to support consistency and quality.

Cannabis products used as food ingredients should be on a level playing field with other food ingredients and products that may be offered to consumers.

C. Some *Cannabis* **products are intended as dietary supplements.** For example, CBD oil is of interest for its antioxidant properties, or to support proper functioning of the human endocannabinoid system.[1] This type of product generally fits the FD&C Act definition of a "dietary supplement," which currently allows the marketing of botanical (and other) preparations[2] taken by mouth as tablets, chewable tablets, chewable lozenges ("gummies"), capsules, powders, soft gels, gel caps, liquids such as syrups, suspensions or certain other forms intended to supplement the diet. Dietary supplements are authorized to describe documented mechanisms by which they help maintain the structure or a function of the body. These products may not, however, claim to diagnose, cure, mitigate, treat, or prevent disease (the latter products would be deemed "drugs").

Dietary supplements are subject to FDA regulation and oversight. The Dietary Supplement Health and Education Act of 1994 ("DSHEA") added specific supplement provisions to the FDCA. The statutory provisions distinguish certain historically-used ingredients from new dietary ingredients; for the latter, safety information must be submitted to FDA on a premarket basis. FDA has promulgated GMP requirements specific to dietary supplements. The Act, as amended, also requires reporting of serious adverse events that may be associated with marketed supplements.

Legislative Revision. To accommodate the unusual regulatory history of Cannabis as a Schedule I substance, a specific legislative revision will be needed to clarify the option to market appropriately qualified *Cannabis* products under the FD&C Act dietary supplement provisions. Specifically, the Act defines "dietary supplement" to *include* articles that were marketed as dietary supplements before the same article was approved in a "drug" form. Going the other direction, the statute *currently excludes* the possibility to market a compound in dietary supplement form if the compound was previously approved, or formally tested (even if not approved), for a pharmaceutical use. The FD&C Act defines "dietary supplement" to exclude:

[1] http://www.prnewswire.com/news-releases/inergetics-nulief-the-first-branded-cannabinoid-cbd-based-nutritional-supplement-now-available-at-blum-dispensary-oakland-ca-300073165.html

[2] The current definition of "dietary ingredient" includes herbs or other botanicals and concentrates, metabolites, constituents, extracts, or combinations.

> (i) an article that is approved as a drug under section 505 [of the FDCA, i.e., the new drug approval requirements] … or licensed as a biologic under section 351 of the Public Health Service Act …, or
>
> (ii) an article authorized for investigation as a new drug … or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public
>
> which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Without any public process or elaboration of the evidence that it reportedly reviewed, FDA recently stated:

> *Based on available evidence, FDA has concluded that cannabidiol products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act*. Under that provision, if a substance (such as cannabidiol) has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. [FDA cited a 2007 press release about testing an investigational drug (Sativex®; composed of two cannabinoids: CBD (cannabidiol,) and THC (delta 9 tetrahydrocannabinol) being tested for cancer pain.]
>
> There is an exception to section 201(ff)(3)(B)(ii) if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized. However, based on available evidence, FDA has concluded that this is not the case for cannabidiol.... FDA is not aware of any evidence that would call into question its current conclusion that cannabidiol products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act. Interested parties may present the agency with any evidence that they think has bearing on this issue.
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> The pertinent statutory provision should be revised for several reasons. First, because *Cannabis* products have been classified as Schedule I products, they were lawfully restricted from prior marketing under the dietary supplement rubric. Congress must tailor the time restriction for prior marketing to address this unique scenario. **This exception Is warranted because of the truly unique history of CBD and *Cannabis* derived products, and thus we recommend that this exception be likewise unique to CBD and *Cannabis*.**
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> FDA also should be obligated to provide fair consideration to the historical restrictions and not simply be allowed to declare – without any public process -- that CBD is excluded from possible dietary supplement use. Congress can clarify the possibility for

Cannabis products to be manufactured as dietary supplement by a specific statutory revision.

D. **Some products are ingredients in cosmetics.** For example, Aloe Vera is a commonly extracted and used for its skin enhancing quality. It is often recommended by physicians for burn relief. Longstanding safety and labeling requirements apply to cosmetics (i.e., articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance (see 21 U.S.C. § 321(i)). Cannabidiol ("CBD") has been incorporated into dozens of topical skin and cosmetic treatments sold throughout the United States, and the world.

E. **FDA should have jurisdiction to allow routine facility inspections.** At the present time, states are solely responsible for evaluating cannabis facilities operating within their jurisdiction. Many of these states are not adequately trained to properly inspect facilities that should be operating under GMPs. The failures of this type of regime was on full display with the tragedy of New England Compounding, and the deaths that ensued from cross-state distribution of an adulterated and contaminated injectable. Fortunately, there has not been a tragedy of this type in the cannabis industry yet, but that does not outweigh the need for uniform standards for the manufacture and distribution of cannabis-derived products when cross-state distribution becomes permitted.

F. **FDA should apply standards for the safe extraction of cannabinoids.** FDA should put patient safety first and defer to the safest methods of extracting cannabinoids from cannabis plant material. Currently there are a few methods for extracting cannabinoids from the cannabis plant. The safest method, and the most expensive, utilizes super-critical carbon dioxide (CO_2) to extract volatile essential oils (terpenes) and the various cannabinoids present in the plant matter. Since CO_2 is a substantial component of the air we breathe, there are no residual solvents in the extract, and thus zero risk to patients from this process. Other processes are less expensive, and utilize hydrocarbons (benzene, propane, butane, etc.), known carcinogens which leave residual solvents in the plant material or derived products that can then be inhaled or ingested. The argument put forth on those methods is that the amount of hydrocarbon present in the extract is very low. Very low is not zero. Very low has risk. FDA has historically applied standards containing limits on residual solvents and required safety studies to qualify those standards. **Economic justifications for hydrocarbon exposure to patients and consumers should never be the standard when there are zero-risk solutions commonly available.**

Core concepts underlying the existing FDA regulatory regime include safety, substantiation of claims, and access. Time and again, it has been clear that American consumers can be trusted to understand information -- including truthful, non-misleading scientific

information -- and to judge what products may be right for them.[3] There is legitimate industry striving to make and market useful, accurately represented products to the consuming public.

III. CANNABIS PRODUCTS SHOULD BE DE-SCHEDULED

The Food and Drug Administration (FDA) shares a role in the scheduling of controlled substances with the Drug Enforcement Agency (DEA). DEA relies on guidance from FDA as to the scientific rationale for abuse potential in their deliberations on whether to designate a particular compound as a controlled substance, or what "schedule" is most appropriate. We believe the scientific evidence is lacking to justify scheduling *Cannabis* and there are thousands of years of safe use to justify de-scheduling.

Cannabis has been used for health-related purposes for almost five millennia. As early as 2727 BC, the Chinese Emperor Shen Nung reported positive effects from *Cannabis* in relieving pain associated with rheumatism and gout. Only in recent history has Cannabis been villainized with respect to psychoactive effects of certain products on certain users. Alcohol similarly faced the Prohibition era; however, that product is now reasonably regulated and available for consumer choice.

Any consumer product may have negative effects, depending how it is used. Pharmaceutical products, for example, undergo rigorous testing to elucidate not only their positive health benefits, but also their risks. A key regulatory activity for all product developers under the FD&C Act (regardless of regulatory classification as a drug, food, or supplement) is to understand and to communicate potential uses *and* associated risks, in order to enable consumers (and, if applicable, their physicians) to make informed choices and to determine how to use individual products.

A. Medical and Health Acceptance

The scientific and medical understanding of *Cannabis* products has developed with time and experience. Federal regulation has not kept up, however. In 1970, *Cannabis* products were deemed to lack currently accepted medical use and assigned to Schedule I under the CSA. Research since then has been stifled by the Federal government in various ways. Nevertheless, current evidence shows that there is medical and other health-supportive demand for *Cannabis* products.

These products should not be without oversight, but they should be de-scheduled because current evidence shows they do not meet the criteria for extraordinary control under the CSA.

[3] See, for example, the Congressional findings underpinning the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), which created the current rubric in the FDCA: "Consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements." FDA has an oversight role (e.g., notification of marketing and safety information may be required to be submitted; the agency can take enforcement action against products that do not comply with applicable requirements).

Regulatory determinations also need to be compound-specific. More than 100 compounds have been identified within the *Cannabis* plant, including numerous native terpenes and cannabinoids (collectively referred to as "Cannabinoids"). The most commonly known Cannabinoid is delta-9-tetrahydrocannabinol ("THC"). This is the compound within *Cannabis* that can have psychoactive effect. FDA has approved a synthetic form of THC (dronabinol; brand name Marinol® Capsules) for the treatment of nausea and vomiting associated with chemotherapy in certain patients.

In an August 11, 2016 press release, the DEA reaffirmed the position that there is currently "no accepted medical use" of *Cannabis*, and that *Cannabis* could not be used safely under medical supervision. Americans for Safe Access ("ASA") estimated in their 2018 Annual Report that there are over 2 million medical cannabis patients in the United States including over 290 thousand in Florida, over 197 thousand in Arizona, over 94 thousand in Maryland, and even 121 thousand in Oklahoma."

Additionally, the DEA has published that there have been no deaths caused by *Cannabis* overdose.[4]

Medicinal or health supporting qualities exist in other Cannabinoids including, but not limited, to Cannabidiol ("CBD"), Cannabidiolic Acid ("CBDa"), Tetrahydrocannabivarin ("THCV"), Tetrahydrocannabivarinic Acid ("THCVa"), and Cannabichromene ("CBC"). For example, CBD may relieve pain and lower inflammation. CBD also may be used to support certain healthy functions (such as antioxidant properties supporting healthy cell function). Unlike THC, CBD and the other listed compounds do *not* have psychoactive effect.

B. Physical and Psychological Dependence

Compared to the non-scheduled substances nicotine and alcohol, and Schedule I substance cocaine, the lifetime probability of physical dependence is lowest with *Cannabis*. As one example, the lifetime probability for nicotine dependence was reported at 67.5%; alcohol at 22.7%; cocaine at 20.9%; *Cannabis* at 8.9%.[5] In regard to psychological dependence, a 1968 study revealed "personality rather than pharmacological factors are the prime consideration" for abusers.[6] This finding is also represented in National Institute for Drug Abuse ("NIDA") executive Dr. Jack E. Henningfield's opinion that marijuana has less potential for psychological dependence than nicotine, alcohol, or cocaine.[7]

[4] https://www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf#page=84
[5] Lopez-Quintero, Catalina et al. "Probability and Predictors of Transition from First Use to Dependence on Nicotine, Alcohol, Cannabis, and Cocaine: Results of the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC)." Drug and alcohol dependence 115.1-2 (2011): 120–130. PMC. Web. 28 Apr. 2016.
[6] http://www.drugtext.org/Cannabis-marijuana-hashisch/acute-and-chronic-toxicity-of-marijuana.html
[7] http://www.drugsense.org/tfy/addictvn.htm

C. Toxicity

There have been no reported deaths from *Cannabis* according to the DEA.[8] It is estimated that the lethal dose for a 150-pound man is roughly nineteen pounds of *Cannabis*, an amount which is essentially impossible to consume.[9]

D. Summary

A full and fair evaluation of *Cannabis* products under the standards set forth in the CSA demonstrate that de-scheduling is appropriate, and the current extraordinary controls governing the same are unnecessary for the protection of public health. This is not to say that *Cannabis* products should be unregulated. Rather, a fundamentally appropriate regime exists, as described in Section II (above).

IV. STATES MUST MAINTAIN RESPONSIBILITY TO DETERMINE WHICH OUTLETS CAN SELL CANNABIS PRODUCTS IN THEIR JURISDICTION

Even when uniform safety and quality standards for *Cannabis* products apply under the FD&C Act, the States should retain clear authority to determine which providers or outlets are qualified to distribute and sell these products. Many States have established regulatory commissions to make medical *Cannabis* available to qualifying patients and otherwise regulated access to *Cannabis* products. In addition, States' boards of pharmacy, state food and drug agencies, and local health departments routinely determine the qualifications and issue licenses to distributors of FDA-regulated consumer products (e.g., wholesale drug distributor permits; pharmacy permits; retail food permits). Preserving State and local oversight is further justified by the novelty of lawful *Cannabis* products and may provide added assurance of proper control, given the debate that has surrounded *Cannabis* products.

Again, the Act already contains relevant precedent, shown in the 2009 amendment of that statute by the Family Smoking Prevention and Tobacco Control Act. When granting FDA various regulatory authority over cigarettes and other tobacco products, Congress included Section 916, titled "Preservation of State and Local Authority." With minor revision to specifically address *Cannabis* products, similar language would achieve the Federal/State allocation appropriate here:

> SEC. 916. PRESERVATION OF STATE AND LOCAL AUTHORITY.
>
> "(a) IN GENERAL. –
>
> "(1) PRESERVATION.–Except as provided in paragraph (2)(A), nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law,

[8] https://www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf#page=84
[9] http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubs-drug-cannab2-ch52.htm

rule, regulation, or other measure with respect to Cannabis products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of Cannabis products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for Cannabis products. No provision of this chapter shall limit or otherwise affect any State, tribal, or local taxation of Cannabis products.

"(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS. —

"(A) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a Cannabis product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to Cannabis product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk Cannabis products.

"(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, *Cannabis* products by individuals of any age, or relating to fire safety standards for Cannabis products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State."

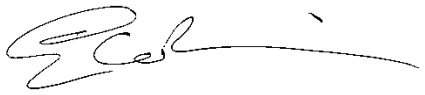
V. SUMMARY

FDA should apply the same quality standards as now exist for dietary supplements to Cannabis and Cannabis-Derived products to assure patient safety. These efforts should include facility inspections, operating standards such as cGMPs and product quality standards to address residual solvents from the extraction process as well as other product quality standards. Patient and consumer safety should be the guiding principle for these efforts.

For the myriad reasons stated above, Cannabis should no longer be scheduled, and Congress should specifically act to de-schedule it under the CSA. Yet, Congress should not leave Cannabis products unregulated -- there is an existing regulatory rubric under the FD&C Act that already provides key framework (including regulatory oversight) for certain aspects of the production, marketing, and distribution of *Cannabis* products. In addition, express clarification is warranted that States have an ongoing role to control the outlets through which *Cannabis* products may be sold and distributed.

Targeted modification of existing statutory language is appropriate given the unique regulatory history of Cannabis products, and this exception should likewise be unique to Cannabis and Cannabis-derived products. Thus, at the same time Congress de-schedules cannabis products, Congress should subject such products to appropriate regulation under the Act. By doing so, Congress can restore the balance between the Federal and State governments and ensure appropriate regulation of Cannabis products consistent with foods, drugs and dietary supplements.

Respectfully submitted,



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