Council For Federal Cannabis Regulation

August 18, 2023

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Bernie Sanders
Chair
Committee on Health, Education, Labor, and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor, and Pensions
U.S. Senate
Washington, DC 20510

RE: Comments Related to Request for Information Regarding Hemp-Derived Products

The Council for Federal Cannabis Regulation ("CFCR") greatly appreciates the opportunity to submit comments to the United States Congress regarding the regulation of hemp-derived consumer products.

CFCR is a non-partisan, 501(c)(3), non-profit organization based in Washington, D.C., that works as a trusted steward, to assist the federal government, its regulatory agencies, and industry to implement evidence-based cannabis oversight and regulation. CFCR's overarching goal is the de-stigmatization, normalization, and legitimization of cannabis on behalf of consumers, along with the professions, organizations, and businesses that support and serve them. We do this by serving as a conduit for informed scientific research, inclusive education, and mainstreaming best practices that ensure consumers have access to safe and well-labeled cannabis products.

Our comments below address the specific questions raised by Congress's Request for Information.

We would be happy to discuss these comments in further detail with you and your staff.

CFCR would appreciate the opportunity to supplement the information below and be pleased to partner with your Committees as you develop federal policy on these issues.

I. INTRODUCTION

Cannabidiol ("CBD") is a non-psychoactive compound found in the *Cannabis Sativa* plant.[1] CBD and other cannabinoids have seen an enormous increase in demand from consumers in the last decade mainly due to their perceived therapeutic effects. Because of this enormous demand, there have been a variety of state and federal efforts to ensure that consumers can access products with these ingredients.

In an effort to eliminate a significant barrier to growth of the domestic hemp market, Congress included provisions in the Agriculture Improvement Act of 2018 ("the 2018 Farm Bill") to redefine the legal border between hemp and marijuana.[2] This opened up a federally legal market for various cannabinoid products derived from hemp.

After passage of the 2018 Farm Bill, products that contained CBD or other cannabinoids derived from hemp and that contained no more than 0.3 percent Delta-9 tetrahydrocannabinol concentration on a dry weight basis were no longer controlled substances under the law.[3] As a result, the Drug Enforcement Administration ("DEA") could no longer prohibit these substances from being sold. Nevertheless, the Food and Drug Administration ("FDA") retains regulatory authority to control these products because the FDA regulates the sale and marketing of dietary supplement products, food products, cosmetic products, and drug products under the authorities established by Congress in the Federal Food, Drug, and Cosmetic Act ("FFDCA").[4]

FDA has stated that CBD cannot be used as an ingredient in food or dietary supplements due to certain exclusionary clauses in the FFDCA that prohibit such use if the substance at issue is an active ingredient in an approved drug product or 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.[5] On January 26, 2023, FDA issued a statement announcing that even if the exclusionary clauses did not apply, FDA would still need "a

[1] Cannabis sativa contains a variety of bioactive compounds such as cannabinoids, flavonoids, phenolics, terpenes, and alkaloids. Liu, Y., et al., TrAC Trends in Analytical Chemistry, Vol. 149, *Cannabis sativa bioactive compounds and their extraction, separation, purification, and identification technologies: An updated review* (April 2022). Although scientists have identified hundreds of cannabinoids in the plant, CBD, and tetrahydrocannabinol ("THC"), the principal psychoactive cannabinoid found in the plant, have largely been the focus of research to date.

[2] Agriculture Improvement Act of 2018, Pub. L. 115-334, 132 Stat. 4908–09 (2018).

[3] 7 U.S.C. § 1639o(1); 21 U.S.C. § 802(16)(B)(i).

[4] 21 U.S.C. §§ 301, *et seq.*

[5] *See* FDA, "FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)" (current as of July 2023) *available at* https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#:~:text=Based%20on%20available%20evidence%2C%20FDA,)(3)(B)%5D (referencing 21 U.S.C. § 331(ll) and 21 U.S.C. § 321(ff)(3)(B)).

new regulatory pathway for CBD" instead of using the existing regulatory regime to safely regulate CBD products.[6] Furthermore, FDA stated that "existing foods and dietary supplement authorities provide only limited tools for managing many of the risks associated with CBD products" and that "is not apparent how CBD products could meet safety standards for dietary supplements or food additives."[7] Thus, FDA stated that it was interested in "working with Congress to develop a cross-agency strategy for the regulation of these products to protect the public's health and safety."[8] In response to FDA's position that it needs authority from Congress to proceed to regulate CBD and other cannabinoid products, Congress has issued this Request for Information.

A. FDA Can and Should Regulate CBD Now Through Enforcement Policy Guidance

CFCR does not take any position on FDA's need to create a new regulatory regime. However, CFCR believes that FDA does have an option to help regulate CBD and cannabinoids while Congress and FDA determine the best regulatory strategy for these cannabinoid products. Specifically, CFCR believes that FDA can and should regulate these products through its enforcement discretion powers and enforcement policy. FDA has the sole authority to enforce the FFDCA, and there is no private right of action for FFDCA violations.[9] Thus, through FDA's decision not to enforce certain provisions, it can create regulatory policy.

FDA has previously used its enforcement discretion and enforcement policy to allow certain products to remain on the market while the products move towards a more established legal framework. For example, FDA has put out specific compliance policy guides regarding unapproved new drugs[10] as well as a guidance policy on specific unapproved new urinary drugs.[11] FDA has also allowed other unapproved new drug products to remain on the market for years and

[6] *See* FDA, "FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward" (Jan. 2023) *available at* https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol.

[7] *Id.*

[8] *Id.*

[9] 21 U.S.C. § 337(a); *see also POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014) (noting "the [FFDCA] and its regulations provide the United States with nearly exclusive enforcement authority," and "[p]rivate parties may not bring enforcement suits."); *Loreto v. Procter & Gamble*, 737 F.Supp. 2d 909 (S.D. Ohio 2010).

[10] *See e.g.* 71 Fed. Reg. 33466, "Guidance on Marketed Unapproved Drugs — Compliance Policy Guide" (June 2006) *available at* https://www.federalregister.gov/documents/2006/06/09/E6-9032/guidance-on-marketed-unapproved-drugs-compliance-policy-guide-availability; *see also* 76 Fed. Reg. 58398, "Revised Guidance on Marketed Unapproved Drugs; Compliance Policy Guide Sec. 440.100; Marketed New Drugs Without Approved NDAs or ANDAs" (Sept. 2011) *available at* https://www.federalregister.gov/documents/2011/09/21/2011-24316/revised-guidance-on-marketed-unapproved-drugs-compliance-policy-guide-sec-440100-marketed-new-drugs.

[11] FDA, "CPG Sec. 430.400 Urinary Preparations - Misbranding - Lack of Rx Legend and Claims" (Mar. 1995) *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-430400-urinary-preparations-misbranding-lack-rx-legend-and-claims.

during this time, it allowed applicants to work to obtain new drug approvals.[12]

CFCR believes that it would be beneficial for FDA, during this interim period where Congress and FDA work to establish a specific regulatory framework for CBD and cannabinoid products, to exercise enforcement discretion and develop specific enforcement guidance that appropriately balances the need for consumer access and consumer safety with respect to these products. Such an enforcement policy guidance would help ensure, in the interim, that: (1) manufacturers protect the public by producing products with adequate labeling, specific warnings, and maximum daily amounts for ingredients; (2) retailers do not stock products that fall outside FDA's enforcement guidelines; and (3) consumers can still access cannabinoid products that they demand while having some regulatory protections prior to new legislation.

CFCR believes that creating a clear enforcement policy establishing FDA priorities for enforcement, or lack thereof, against certain CBD and cannabinoid products that meet certain requirements is the best policy to help bridge the time until a more comprehensive cannabis policy can be enacted.

The remainder of these comments will focus on responding to Congress's specific questions in its Request for Information.

[12] *See e.g.* 69 Fed. Reg. 23,409, "Exocrine Pancreatic Insufficiency Drug Products" (Apr. 28, 2004) (regarding FDA's position that pancreatic insufficiency products are now classified as drug products and allowing manufacturers four years to market their product while they work on obtaining an approved new drug applications).

II. RESPONSE TO CONGRESSIONAL INQUIRY

Current Market Dynamics

1. **What does the current market for CBD products look like? Please describe the types and forms of products available, manufacturing practices within the industry, market supply chain, how products are marketed and sold, the types of cannabinoids used in products, the marketed effects of CBD products, and the range of CBD doses currently found in the market.**

The types and forms of CBD products available on the market are varied. They include ingestibles (e.g., gummies, soft gels, capsules, tinctures, food, and beverages), dissolvables (e.g., strips, mints, oral sprays), topicals (e.g., creams, balms, salves, plasters, sprays, patches), as well as inhalables and other dosage forms. There are also a variety of cannabinoids that have followed the influx of CBD based products, including cannabinol and cannabigerol.

With respect to manufacturing practices, there are a number of current Good Manufacturing Practices ("cGMP") certified cannabinoid manufacturers supporting the market. Despite the backdrop of uncertainty given the lack of regulatory clarity, these handful of high-quality manufacturers are doing an excellent job at navigating the existing regulatory framework. Nevertheless, because brands are limited to this small number of manufacturers supporting the majority of the compliant market, an imbalance of power when negotiating terms for variety of end products is created.

Additionally, the absence of dosing standards has resulted in a wide range of dosages available in the market. This is then exacerbated by the hemp-derived Delta-9 and Delta-8 based products that have entered the market in the past twelve months creating more concern for regulators from a public safety perspective, given the unknowingly toxic and impairing nature of these cannabinoids.

There is a distinct need for education to support consumers as they navigate these product categories and learn which product type and dosage is suitable for their individual needs. In the absence of guidance around dosage, consumers are at risk of consuming high-dose products with problematic effects.

As to the marketing and sale of CBD products, marketing options are confusing. For example, some social media platforms are comfortable with hemp-derived cannabinoid-based brands promoting their products while others have been selective in what products they allow to be promoted. Moreover, service providers have been selective in how they support brands with hemp-derived ingredients and will randomly discontinue supporting brands based on internal assessments that are often unclear to the brands, who believe they have acted in a compliant manner. This uncertainty has placed a heavy burden on brands that are investing significant dollars in marketing strategies and execution while being highly vulnerable to sudden closing of accounts.

CFCR believes that the establishment of minimum guidance regarding these classes of products is imperative. Such minimum guidance provided by the government will ensure clarity

among the industry, prevent bad actors from entering or competing in the marketplace, and protect consumers.

2. How has the market changed since the passage of the 2018 Farm Bill?

Based on the experiences of CFCR members, the passage of the 2018 Farm Bill significantly changed the marketplace for CBD products. For example, the change to the regulatory definition of hemp substances itself resulted in thousands of CBD brands, distributed through a range of customer end points, entering the market.

This has not only allowed bad actors to participate in a market that is infrequently regulated but created confusion for consumers. Moreover, because of this intense competition, good faith manufacturers have been challenged to engage with consumers in a standardized way and are competing with inefficacious products and false labeling that creates mistrust. As a result, consumers have no ability to differentiate between a safe and unsafe product.

3. How is the lack of national standards for CBD products affecting the market?

The lack of national standards for CBD products affects both the medical and adult-use hemp and legal cannabis markets and consequently consumers and businesses.

First, this lack of standardization has resulted in inconsistent product quality. Without standardized regulations, the quality and safety of CBD products can vary widely. This, in turn, makes it challenging for healthcare professionals to recommend products confidently. This also erodes consumer trust and can lead to negative experiences, hindering the overall reputation of the industry.

Second, in the absence of clear regulations, there is a higher risk of unsafe or mislabeled products entering the market. Consumers may unknowingly purchase products with incorrect potency, harmful contaminants, or misleading labeling. This can lead to adverse health effects and undermine the perceived benefits of CBD.

Third, differences in rules between states can result in confusion for manufacturers, retailers, and consumers. This makes it even more difficult for businesses to operate in the hemp and cannabis markets. In fact, this lack of clarity impedes the growth of the industry and discourages investment due to potential legal risks.

To address these issues, among others, CFCR proposes that FDA establish clear standards for CBD products through policy guidance. Such standards would help ensure consistent quality, safety, and transparency, while also ensuring suitable growth and innovation in the cannabis markets.

Pathway

4. **Please comment on the concerns FDA has raised with regard to regulating most CBD products through existing pathways (i.e., conventional foods, dietary supplements, and cosmetics), and FDA's view that there is a need for a new regulatory pathway for CBD products. If existing regulatory pathways are sufficient for regulating CBD products, please explain how these existing pathways can be used to address the concerns raised by FDA, as appropriate.**

FDA has expressed that CBD cannot be used in dietary supplements or food products due to the exclusionary provisions in the FFDCA[13] and cannot be regulated within the frameworks set forth for such products due to safety reasons.[14] Therefore, FDA has requested Congress to create a new regulatory framework from which it could regulate CBD.

CFCR does not take a specific position on the current legality of CBD and cannabinoids in food and dietary supplements or whether CBD could be regulated within the frameworks for such products. Nevertheless, CFCR believes that it would be beneficial for FDA, during this interim period where Congress and FDA work to establish a specific regulatory framework for CBD and cannabinoid products, to exercise enforcement discretion and develop clear enforcement policy establishing FDA priorities for enforcement, or lack thereof, against certain such products.

FDA has the sole authority to enforce the FFDCA as there is no private right of action to enforce the FFDCA.[15] Thus, through FDA's decision not to enforce certain provisions, it can create regulatory policy. FDA has previously used its enforcement discretion and enforcement policy to allow certain products to remain on the market while the products move towards a more established legal framework. For example, FDA has utilized a compliance policy guide to established how FDA intended to allow certain unapproved drugs to continue to be marketed and sold in the United Stated despite not having an approved New Drug Application or Abbreviated New Drug Application from FDA.[16]

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[13] *See* FDA, "FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)" (current as of July 2023) *available at* https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#:~:text=Based%20on%20available%20evidence%2C%20FDA,)(3)(B)%5D (referencing 21 U.S.C. § 331(ll) and 21 U.S.C. § 321(ff)(3)(B)).

[14] *See* FDA, "FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward" (Jan. 2023) *available at* https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol.

[15] 21 U.S.C. § 337(a); *see also POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. at 109 (2014); *Loreto v. Procter & Gamble*, 737 F.Supp. 2d 909 (S.D. Ohio 2010).

[16] *See e.g.* 71 Fed. Reg. 33,466, "Guidance on Marketed Unapproved Drugs — Compliance Policy Guide" (Jun. 2006) *available at* https://www.federalregister.gov/documents/2006/06/09/E6-9032/guidance-on-marketed-unapproved-drugs-compliance-policy-guide-availability; *see also* 76 Fed. Reg. 58398, "Revised Guidance on Marketed Unapproved Drugs; Compliance Policy Guide Sec. 440.100; Marketed New Drugs Without Approved NDAs or ANDAs" (Sep. 2011) *available at* https://www.federalregister.gov/documents/2011/09/21/2011-24316/revised-guidance-on-marketed-unapproved-drugs-compliance-policy-guide-sec-440100-marketed-new-drugs.

Moreover, FDA recognizes that in certain circumstances it makes more sense to allow a product on the market than to try to take enforcement action against all these products. Should FDA determine to forgo enforcement as to specific provisions under the law, certain CBD and cannabinoid products could legally remain on the market.

CFCR believes that the creation of an enforcement policy guidance for CBD and cannabinoid products would allow FDA to provide, albeit temporarily, clear requirements for warnings, dosage limits, acceptable ingredients, and proposed labeling. In turn, this would allow FDA to ensure that consumers are given sufficient access to and protection from cannabinoid products as FDA and Congress determine the best pathway for CBD regulation.

Scope

5. **How should CBD and/or cannabinoid-containing hemp products be defined? What compounds should be included and excluded from a regulatory framework?**

CFCR does not take a specific position on how CBD and cannabinoid-containing hemp products should be defined under any proposed legislation. However, CFCR does request that Congress ensure consumers and patients continue to have access to cannabinoid products that the public has found beneficial.

   a. **Should Congress or FDA limit the amount of intoxicating or potentially intoxicating substances produced by *Cannabis sativa L*. in food and dietary supplements? Which substances, if any, warrant greater concern? How should these substances of concern be addressed? What products, if any, should not be allowed on the market?**

In general, CFCR believes that consumer cannabinoid products that are sold outside of a state's medical or recreational marijuana legal structure should not be unknowingly impairing or toxic. Thus, CFCR would support a clear statement from FDA that the Agency would not allow consumer products to contain substances in amounts that could unknowingly impair or be toxic to users.

Additionally, CFCR takes the position that to avoid continued confusion in understanding the specific drug-effect relationship, the term "Intoxicating" warrants clarification and more precise application, based on actual toxicity-related outcomes for substances that are indeed known to be toxic to the biological systems and indicated through the measured levels of systematic effects.

   b. **How should Congress or FDA identify appropriate limits for THC and other cannabinoids in finished products? Relatedly, how should a framework account for "total THC," including tetrahydrocannabinol acid (THCA), in FDA's regulation of intermediate and finished products?**

CFCR does not have a specific position on how FDA should identify the appropriate limits for THC or other cannabinoids in finished consumer products. Nevertheless, FDA should ensure

that consumers do not inadvertently have access to products that that could unknowingly impair or be toxic to users.

c. Should FDA regulate the manufacture and sale of "semisynthetic derivatives," or "biosynthetic cannabinoids," which are still scheduled under the CSA?

FDA regulates all substances that are sold as food, drugs, dietary supplements, or cosmetics. Thus, to ensure sufficient and consistent regulation, CFCR believes that FDA should continue to regulate such products whether the source of the cannabinoids is synthetic or natural.

6. Other non-cannabinoid products are available on the market that have raised safety concerns among some individuals, which FDA has regulated without a substance-specific regulatory framework (e.g., kratom, caffeine, etc.). How has FDA dealt with products containing those substances? How might these products be implicated by a CBD-specific product framework?

CFCR recognizes that the ability for FDA and DEA to regulate certain products that have raised safety concerns absent substance-specific regulatory frameworks is important. Should a regulatory framework for CBD products be established, CFCR does not believe that the ability of FDA and DEA to regulate other areas would be diminished. Thus, concerns regarding this should not be a barrier to establishing such a framework.

FDA regulation of kratom occurred mainly through public health advisories and warning letters.[17] Similarly, DEA has issued regulation of kratom mainly through resource guides and press releases.[18] Kratom, formally known as *Mitragyna speciosa*, is a botanical substance derived from

[17] *See e.g.* Warning Letter to Cali Botanicals, MARCS-CMS 575320 (June 11, 2019) *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cali-botanicals-llc-575320-06112019; *see also*, Warning Letter to KratomNC, MARCS-CMS 576964 (May 16, 2019) *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kratomnc-576964-05162019; Warning Letter to Herbsens Botanicals, MARCS-CMS 634373 (June 30, 2022) *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/herbsens-botanicals-634373-06302022; Warning Letter to Klarity Kratom, MARCS-CMS 634501 (June 30, 2022) *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/klarity-kratom-634501-06302022; Warning Letter to Kratom Exchange, MARCS-CMS 633972 (June 30, 2022) *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kratom-exchange-633972-06302022; Warning Letter to Omni Consumer Products LLC d/b/a YoKratom, MARCS-CMS 634184 (June 30, 2022) *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/omni-consumer-products-llc-dba-yokratom-634184-06302022.

[18] *See* DEA, "Drugs of Abuse a DEA Resource Guide", 2017 Edition, *available at* https://www.dea.gov/sites/default/files/pr/multimedia-library/publications/drug_of_abuse.pdf; *see also* DEA Press Release, "DEA Announces Intent To Schedule Kratom" (Aug. 31, 2016) *available at* https://www.dea.gov/press-releases/2016/08/30/dea-announces-intent-schedule-kratom (announcing the intent to schedule Kratom and its two psychoactive compounds as Schedule I substances under the emergency scheduling provisions of the Controlled Substances Act).

a leafy Southeast Asian tree.[19] Kratom contains certain chemical compounds, which have been indicated to cause both narcotic and stimulant-like effects.[20] Given its chemical makeup, concerns exist regarding the toxicity of kratom in multiple organ systems.[21] FDA has reported that kratom consumption can lead to, *inter alia*, respiratory depression, vomiting, nervousness, weight loss, constipation, and withdrawal-like symptoms including hostility, aggression, excessive tearing, muscle and bone aches, and jerky limb movements.[22]

With regard to "pure and highly concentrated caffeine", FDA has also taken a strong position to limit the sale of these substances. In 2015 and 2016, the FDA issued warning letters to five distributors of pure powdered caffeine products.[23] Later, the FDA incorporated some of the notions touched on in these warning letters and issued guidance to manufacturers of dietary supplements containing high concentrations of caffeine.[24] The Guidance sought to inform "firms that manufacture, market, or distribute dietary supplement products that contain pure or highly concentrated caffeine, or [were] considering doing so," and to explain conditions under which the FDA would consider a product containing highly concentrated caffeine to be adulterated.[25]

The FDA's monitoring of products, as seen with dietary supplements containing highly concentrated amounts of caffeine and with kratom, demonstrates that a substance-specific regulatory framework is not immediately required for the FDA to begin regulating hemp-derived compounds. Moreover, if the FDA were to establish a specific framework for CBD products, CFCR does not believe that FDA's ability to regulate certain products that have raised safety

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[19] FDA News Release, "US Marshals seize dietary supplements containing kratom" (Jan. 6, 2016) *available at* https://www.fda.gov/news-events/press-announcements/us-marshals-seize-dietary-supplements-containing-kratom#:~:text=The%20U.S.%20Food%20and%20Drug,supplements%20labeled%20as%20containing%20kratom.

[20] *Id.*; *see also*, NIH National Institute on Drug Abuse, Drug Facts: Kratom, *available at* https://nida.nih.gov/sites/default/files/drugfacts-kratom.pdf.

[21] *Id.*

[22] *Id.*

[23] *See* FDA, *Pure and Highly Concentrated Caffeine* (current as of Mar. 2023) *available at* https://www.fda.gov/food/dietary-supplement-ingredient-directory/pure-and-highly-concentrated-caffeine referring to Warning Letter to Global Marketing Enterprises, CHI-3-16 (Mar. 15, 2016) *available at* https://wayback.archiveit.org/7993/20190207213351/https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm518519.htm; Warning Letter to Bridge City LLC (Aug. 27, 2015) *available at* https://wayback.archive-it.org/7993/20161022183847/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm460203.htm; Warning Letter to Hard Eight Nutrition, LLC (Aug. 27, 2015) *available at* https://wayback.archive-it.org/7993/20161022183846/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm460200.htm; Warning Letter to Kreativ Health Inc. (Aug. 27, 2015) https://wayback.archive-it.org/7993/20161022183845/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm460208.htm; Warning Letter to Purebulk, Inc. (Aug. 27, 2015) *available at* https://wayback.archive-it.org/7993/20201218171804/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/purebulk-08272015.

[24] *See* FDA, "Highly Concentrated Caffeine in Dietary Supplements: Guidance for Industry" (Apr. 2018) *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-highly-concentrated-caffeine-dietary-supplements.

[25] *Id.* at 1.

concerns absent substance-specific regulatory frameworks would be diminished, and thus that should be no barrier for establishing such a framework.

At this time, potential paths forward include the following steps: (1) FDA should begin regulating hemp-derived CBD products through use of the agency's enforcement discretion; and (2) Congress and the FDA should begin working together to determine what hemp-derived CBD products should remain on the market and available to consumers.

On the first point, the FDA can exercise its discretion not to enforce certain regulatory requirements related to hemp-derived CBD products. The FDA can also issue guidance to manufacturers that sets forth the agency's thinking on hemp-derived CBD products as well as recommendations on how to formulate and market products that do not present a risk of illness or injury. Like with highly caffeinated products, the FDA can issue warning letters to manufacturers that address products considered to be a threat to public health.

7. **How has the absence of federal regulation over CBD created a market for intoxicating, synthetically-produced compounds, such as Delta-8 THC, THC-O, THC-B, HHC-P, and others?**

Without federal guidance over CBD products, and in combination with consumer desire to have access to THC products in prohibition states and on a federal level, there has been a supply of products that contain compounds identifying as cannabinoids entering into the consumer market without any human consumption studies or FDA food or supplement oversight to these products.

Cannabis Sativa, as a biologic, contains hundreds of compounds most of which we are only beginning to study. The main compounds consumers are currently utilizing as supplements and therapeutics are CBD and Delta 9-THC. Without legalization and clear enforcement policy at a federal level in place, resourceful and unscrupulous industry actors will find their way around into the market and will continue to create synthetically-derived, lab productions of Delta 8-THC, THC-O, THC-B, HHC-P. That is why CFCR is supportive of FDA creating specific enforcement policy to ensure that FDA prioritizes protecting consumers from toxic and unknowingly impairing products.

a. **What is the public health impact of these novel compounds?**

Despite the lack of scientific studies on the effects of human consumption, these compounds, which were originally laboratory research compounds, have been found in the unregulated consumer market. For example, products containing such compounds are now being marketed as a legal product with effects similar to Delta 9-THC in convenience stores and gas stations around the country.

There is no clear oversight of these products as they fall out of the state regulated medical and recreations marijuana programs, and out of United States Department of Agriculture jurisdiction post cultivation. While FDA has the authority to take action against these products, and has done so on certain occasions, FDA has yet to establish clear guidance to ensure that these products do not enter the market. These products have become a specific public health danger, attracting the most vulnerable patients looking to support unmet medical needs, consumers looking

for supplemental support for wellbeing products, and the curiosity of individuals looking for certain psychoactive effect. CFCR members know of adverse events reported to poison control centers include nausea, vomiting, intoxication, dizziness, confusion, anxiety, tremors, and loss of consciousness.

b. How have FDA and state regulators enforced against products containing these compounds?

As of July 2023, Delta 8 is available in 29 states, and the District of Columbia. Some states have regulated such products within the cannabis state programs.

FDA has also taken a variety of enforcement actions regarding products of unknown toxicity and impairment. Recently, on July 5, 2023, the FDA and FTC released six warning letters to companies selling Delta 8 products.[26] The products at issue were marketed to vulnerable populations, including children, through copy-cat packaging and labeling of well-known legal marketed snacks and candy.

c. How should Congress consider the inclusion of these products in a regulatory framework for cannabinoid hemp products, if at all?

As with all products on the market, Congress should consider the need for a regulatory framework for all cannabis, including hemp products such as CBD as well as its derivatives such as Delta 8 and others. This framework should include standardization and oversight of product testing, labeling, marketing, packaging, and safety protocols for the current marketed available forms of administration based on pharmacology, science, and research of these products in relationship to human consumption. Additionally, regulatory oversight and guidance in age, condition, and dosing needs to be prioritized with accessibility considered.

To support the developments and implementation of a new framework, Congress could create a new framework specific to cannabis and cannabinoid products that draws appropriations and expertise from current agencies, educators, and industry compliant stakeholders to support state programs on a federal level. For example, one possibility would be to create a Health Ministry for Cannabis, that includes product safety and testing oversight, research and product development to prioritize harm reduction and public safety, and licensing responsibilities for regulatory compliant businesses to ensure a thriving industry. CFCR does not take a specific position on how Congress should create a new framework and is merely providing some possibilities that Congress may consider.

[26] *See* FDA New Release, "FDA, FTC Warn Six Companies for Illegally Selling Copycat Food Products Containing Delta-8 THC" (July 5, 2023) *available at* https://www.fda.gov/news-events/press-announcements/fda-ftc-warn-six-companies-illegally-selling-copycat-food-products-containing-delta-8-thc.

8. **CBD products are not limited to just ingestible routes of administration—some are interested in products with alternative routes of administration (e.g., inhalable, topical, ophthalmic drops, etc.).**

    a. **For which non-ingestible routes of administration are consumers interested in consuming CBD products?**

Based on our experience from advising companies in the CBD space, products containing CBD span a wide array of administration methods, include anything from beverages, foods, and supplements to cosmetics, pain-relief creams, sublingual drops, aromatherapy devices, e-cigarettes/vapes, suppositories, and eye drops.

    b. **How should a regulatory framework for cannabinoid products account for non-ingestible routes of administration?**

CFCR does not take a specific position on what the regulatory framework should be for non-ingestible routes of administration. CFCR recognizes that for a product to qualify as a dietary supplement or food it must be ingestible according to the FFDCA. CFCR believes that FDA should publish an enforcement policy guide that would allow FDA to regulate all forms of CBD products while Congress and FDA determine the appropriate pathways for CBD products. To the extent that FDA has specific safety concerns regarding a particular route of administration (e.g., ingestion, inhalation), the Agency should alert consumers of these concerns and provide guidance on tolerance levels for the ingredients consumed in the recommended manner.

Federal-State Interaction

9. **In the absence of federal regulation or enforcement over CBD products, many states have established state regulatory programs to safeguard public health and create market certainty for industry participants.**

    a. **Which product standards relating to warning labels, minimum age of sale, manufacturing and testing, ingredient prohibitions, adverse event reporting, and others, have states adopted to protect consumer safety?**

Many different states have created various protections for consumer safety. CFCR could not provide a comprehensive overview of these standards, but CFCR supports Congress reviewing these various state laws in determining what regulations would be appropriate to regulate cannabis products.

    b. **Which such standards, if any, should Congress look to as models?**

CFCR does not have a position on what specific model Congress should follow. However, CFCR recommends Congress follow a model that helps ensure consumer access to CBD products while ensuring that consumers are made aware of and protected from safety risks associated with these products.

10. How should Congress consider federal preemption as it works towards a regulatory pathway? Should states be able to continue to build upon federal regulation of CBD products?

CFCR seeks to ensure that any regulatory regime adopted sufficiently balances consumer access and consumer safety as it relates to CBD products. As such, CFCR does not have a position on whether Congress should create legislation that preempts state law or whether states should be able to have differing regulations for CBD products.

Safety

11. What is currently known about the safety and risk-benefit profile of CBD and other hemp derived cannabinoids? What safety and toxicity data are available to support this knowledge. Please include in your answer any relevant information about safety with regard to specific populations, such as children and pregnant individuals.

Considering its limited time for non-DEA regulated research, there has been a good amount of research on the safety and toxicity of CBD. We have attached a list of references regarding toxicity studies related to CBD to these comments to help inform Congress's decisions.

However, the conclusions of various studies warrant deeper investigation. For example, within the data of these studies, there are reported side effects. The most common side effects of Epidiolex include "somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder, and poor-quality sleep; and infections", in addition to causing mild to severe hepatic impairment in some trials.[27] Comparatively, a separate study concluded: "CBD was generally well tolerated. Most [adverse events] were mild in severity; none were severe or serious. The safety and [pharmacokinetic] profile support twice-daily administration of CBD."[28] Thus, it is important to review all the literature to get a comprehensive understanding of the risk-benefit profile of CBD.

12. What actions, if any, should the Federal government take to better understand the potential benefits or harms of CBD products and other cannabinoids?

CFCR does not propose any specific actions by the Federal government. Nevertheless, CFCR would support any well designed clinical and animal trials that would help further the understanding of the benefits and harms of CBD products along with other cannabinoids.

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[27] *See* Pauli CS, *et al*., "Cannabidiol Drugs Clinical Trial Outcomes and Adverse Effects," Frontiers in Pharmacology, v. 11 art. 63 (Feb. 25, 2020) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7053164/ citing FDA Approved Label for Epidiolex, NDA 210365 (last accessed Aug. 16, 2023) *available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process.

[28] *See* Taylor L, Gidal B, Blakey G, *et al.*, "A Phase I, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose, Multiple Dose, and Food Effect Trial of the Safety, Tolerability and Pharmacokinetics of Highly Purified Cannabidiol in Healthy Subjects," CNS Drugs, v. 32, issue 11 at 1053-1067 (Nov. 2018).

13. **How should a new framework for CBD products balance consumer safety with consumer access?**

CFCR agrees that it is important to create laws that balance consumer safety with consumer access. While consumer demand for CBD products has increased due to their potential therapeutic benefits, the concerns regarding their safety and proper regulation has also increased. CFCR believes that any framework that is developed should have clear regulatory guidelines, appropriate product testing and quality controls, appropriate labeling including warnings regarding daily maximum dosing, age restrictions to prevent underage consumption, and adverse event reporting to understand any new risks associated with the products.

CFCR supports Congress's efforts to find a balance that promotes both consumer safety and access. This will require ongoing collaboration between regulatory bodies, industry stakeholders, healthcare professionals, and consumer advocacy groups to ensure that the framework remains effective and relevant over time.

14. **Some stakeholders have raised concerns that CBD products have inherent risks. What are those inherent risks, and at what levels of CBD do those risks present themselves? What data and other evidence support the existence of such risks, and from which products are such data and evidence derived?**

CFCR does not have any specific information on the inherent risks of CBD products outside of information that can be found in the published literature on CBD.

15. **FDA approved Epidiolex, a drug containing CBD, based in part on a data package that included preclinical data from rodent safety models, as well as clinical trials. FDA has received safety data on CBD products from several manufacturers also based on rodent models. How should FDA consider data submitted for a CBD-containing drug as evidence to support that CBD is safe for human consumption in non-drug products, recognizing the inherent differences in the intended uses of such products?**

It is the role of the FDA to consider all evidence that arises during drug development and when new drugs are released into the market. Data relevance shifts as we learn more about positive and negative side effects and adverse events. Thus, a product's post market, real world evidence-based data needs to be considered when evaluating a product.

As to rodent models, these models should also be considered as such models may be compared to each other and Phase I results from clinical trials that study the safety among healthy adults.

When considering general population consumption, in order to achieve the most harm reduction regulators should prioritize and protect the most vulnerable in dosing with educational labeling, physician supported guidance, and appropriate regulatory restrictions.

16. **Should there be limits on the amount of CBD in foods, dietary supplements, tobacco, or cosmetics? If so:**

    a. **Should Congress or FDA set such limits, recognizing the time it can take to complete the legislative process and the regulatory process at FDA?**

    b. **How should that amount be determined? What should the amount be?**

    c. **Should such limits be applied on the amount per serving, and/or per package?**

    d. **Could FDA set such limits under its current statutory regulatory authorities for foods and dietary supplements to potentially address safety concerns, notwithstanding exclusionary clause issues?**

    e. **How should the experience of states inform the setting of limits on amounts of CBD in products?**

CFCR does not take a position regarding what should be established as the limit on the amount of CBD in various products but believes that any limit created should be established through input from all stakeholders. CFCR also believes that if certain safety risks to consumer exist with certain dosage amounts that FDA should put forth enforcement policy guidance that establishes specific limits for CBD in these products so that it is clear that certain concentrations of CBD will not be tolerated in consumer products due to their danger to consumers.

17. **How should a regulatory framework account for CBD products marketed in combination with other substances that may alter or enhance the effects of CBD (e.g., caffeine, melatonin, etc.)?**

CFCR does not take a position regarding what specific regulatory framework should be established for use of CBD in combination with other substances. However, CFCR supports any framework that would prohibit any products that include combinations of ingredients that are unsafe from entering the market.

18. **What precedent is there for FDA restricting certain otherwise allowable ingredients in legally marketed products? What amount and type of evidence has been required/demonstrated to support any such restrictions?**

In general, FDA allows certain ingredients in certain type of regulated products. Simply because an ingredient has been permitted in one category of FDA-regulated product does not mean that it is automatically permissible in a different category. For example, by statute, an ingredient that is approved as a new drug or being publicly investigated as a new drug cannot also be a dietary supplement ingredient, unless that ingredient was first marketed as a dietary supplement or as a

food prior to the drug approval/investigation.[29] Thus, simply because an ingredient is legally marketed in drug form does not mean that it can also be legally marketed in dietary supplement form. Likewise, a number of dietary ingredients that are permissible in dietary supplements (e.g., melatonin) are not approved food additives or established to be generally recognized as safe ("GRAS") for use in food, and therefore may not be contained in a conventional food product. GRAS status is established through consensus among experts qualified by scientific training and experience to evaluate its safety under the conditions of its intended use.

19. What functional ingredients combined with cannabinoids raise safety concerns?

CFCR does not have any specific information on what functional ingredients along with CBD raise safety concerns outside of information that can be found in the published literature.

Quality

20. How should Congress create an FDA-implemented framework to ensure that manufacturers provide appropriate consumer protections and quality controls?

In the past, in order to establish an FDA framework to regulate a class of products, Congress has legalized the class and given FDA wide authority to ensure that the products are safe and effective for their intended use. Even with products that present difficult issues of balancing consumer access with public health (e.g., tobacco products), Congress has given the statutory authority and the parameters around which FDA can build a regulated framework. CFCR would support Congress doing the same in this situation.

FDA already has shown that it has appropriate frameworks in place which provide robust consumer protections and quality control standards for foods, food ingredients, supplements, cosmetics, animal feeds, and drugs. If CBD is to be regulated outside of these channels, then an adult-use category, similar in nature to those which exist for alcohol or tobacco could be created by Congress. This new framework could enlist cooperation with other regulatory agencies like the Alcohol and Tobacco Tax and Trade Bureau ("TTB"). CFCR does not take a specific position on how Congress should create a new framework and is merely providing some possibilities that Congress may consider.

a. How should such a framework compare to the current Good Manufacturing Practice (GMP) requirements that apply to food, dietary supplements, and cosmetics?

CFCR does not take a specific position on how a cGMP framework for CBD products should be established. CFCR does believe that FDA's cGPM framework utilized for foods, drugs, and cosmetics is clearly established and provides superior consumer protections. Thus, FDA could utilize these channels with additional relative safeguards for CBD products if they were to be included in those regulatory frameworks. Alternatively, FDA and Congress could create an adult-

[29] FFDCA § 201(ff)(3).

use framework mimicking aspects of FDA and TTB regulation where overlapping oversight can occur.

b. Are those food, dietary supplement, and cosmetics GMP frameworks adequate for regulating quality in CBD? Why or why not?

CFCR does not take a specific position on whether these frameworks would be adequate for regulating CBD products. CFCR seeks to ensure that any cGMP framework provide for a specification driven and verified process for consistent product output. CFCR also recommends such framework require formal ingredient level documentation including defining permitted ranges and tolerances of both desired and undesired content, and standards of identity. Lastly, any cGMP framework adopted should have verification testing to ensure validity.

21. What are alternative quality approaches that Congress should consider for CBD products? For example, how should third parties be leveraged for the creation and auditing of manufacturing and testing requirements?

CFCR does not take a specific position on whether Congress should use private third parties to help with the auditing of manufacturing and testing requirements for CBD products.

Form, Packaging, Accessibility, and Labeling

22. What types of claims should product manufacturers be permitted to make about CBD products? Please reference how such permitted claims compare to the types of claims that may be made about drugs, foods, dietary supplements, and cosmetics.

CFCR recognizes the importance of balancing consumer desire for access to CBD products with the regulatory oversight needed to manage risks associated with CBD products and ensure consumer safety. However, we cannot disregard the dangers that come with the lack of regulation and oversight. CFCR believes is better to have temporary regulations and oversight in place, of which enforcement discretion can be used, than none at all. CFCR believes that there are sufficient laws in place that provide, at least temporarily, a clearer understanding of the types of claims normally recognized by federal and state law to be permissible that either do or could easily be expanded to include CBD products. To the extent that FDA and Congress seek to permit wider claims while working to create a new regulatory regime for CBD products, FDA can do so through its use of enforcement discretion and enforcement policy guidance as discussed above.

It should be noted that, regardless of FDA requirements, various federal and state law and regulations require claims made for all products (e.g., tobacco, food, dietary supplements, cosmetics, etc.) to be truthful and not misleading. For example, every state has consumer protection laws that govern advertisements running in that state. Additionally, the Federal Trade Commission ("FTC") requires all advertising and promotional messages to follow truth-in-advertising standards in that any claims made must be truthful, cannot be deceptive or unfair, and

must have objective evidence that supports the claim (i.e., "reasonable basis").[30] CFCR supports the position that any claims made for CBD products should be truthful and not misleading.

Additionally, unless a product is an approved drug product, manufacturers are generally prohibited from making claims that express or imply the product is intended to diagnose, mitigate, treat, or prevent disease, or to affect the structure or function of the body.[31] In fact, while Congress does allow for dietary supplement products to make certain wellness structure/function claims that fall short of drug claims,[32] such claims are strictly limited. Permissible structure/function claims may describe how a particular dietary ingredient affects the structure or function of the body, describe general well-being from consumption of a nutrient or dietary ingredient function or general well-being of the body, or characterize the documented mechanism of action by which a nutrient or dietary ingredient acts to maintain such structure or function.[33] Structure/function claims cannot express or imply an ingredient or product is used to treat diseases or suggest that consumers can and should take dietary supplement products to prevent or treat very serious conditions that would normally require extensive medical intervention and treatment.

Additionally, when making structure/function claims for dietary supplements, the FFDCA requires manufacturers to include a disclaimer statement, prominently displayed and in boldface type, stating its products are "[t]his statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[34] Further, the manufacturer must submit a notification with the text of the claim to FDA no later than 30 days after marketing the dietary supplement with the claim.[35]

CFCR believes that it is better to have temporary regulations and oversight in place, of which enforcement discretion can be used, than none at all. In fact, FDA appears to have already embraced the use of enforcement discretion as it relates to CBD products in only seeking enforcement against certain products that hold substantial risk to the public, particularly vulnerable populations (e.g., products of unknown toxicity and impairment). The temporary use of current regulations like those described herein, modified via the use of enforcement discretion and enforcement policy guidance documents produced by FDA, could easily provide minimum regulations and oversight for CBD products. This, in turn, will help ensure only safe products are being marketed and used by the public until an official regulatory pathway is established.

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[30] See FTC, "Advertising FAQ's: A Guide for Small business" (April 2001, edits Feb. 2023 to reflect Inflation Adjusted Civil Penalty Maximums) *available at* https://www.ftc.gov/tips-advice/business-center/guidance/advertising-faqs-guide-small-business; see also FTC Act § 5 [15 U.S.C. §§ 41-58] (prohibiting "unfair or deceptive acts or practices in or affecting commerce.").

[31] FFDCA § 201(g).

[32] FFDCA §§ 201(g)(ff).

[33] 21 C.F.R. § 101.93(f).

[34] 21 U.S.C. § 343(r)(6)(C) and 21 C.F.R. § 101.93(b).

[35] 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93.

23. What is the evidence regarding the potential benefits of including a symbol or other marking on product labeling to provide clarity for consumers who would purchase products that contain CBD?

CFCR does not have any evidence supporting the use of symbols specifically for CBD products. CFCR merely can identify that FDA has seen that such symbols can greatly benefit consumers by providing clarity regarding products.

In September of 2016, FDA revised its labeling regulations for medical device and certain biological product to explicitly allow for the use of symbols in labeling.[36]

Additionally, a Cambridge University study also suggested that the use of symbol-labeling on menus was an effective communication tool and supported students in making healthier choices.[37] Moreover, while not dealing with a symbol, a different study suggests that location orientation, specifically front of package labeling, provided consumers a variety of health literacy gain perspective therefore influencing the choice of healthier and non-healthier beverages.[38]

24. What are the potential benefits or drawbacks of an additional or substitute standardized label panel for CBD products, compared to the current Nutrition Facts Label and Supplements Label?

CFCR does not have a specific position on the benefits or drawbacks to creating a new standardized label for CBD products that would replace a Nutrition Facts or Supplement Facts Label. CFCR does believe that if Congress were to create a new regulatory category for CBD products that such a category should include labeling information requirements that provide clarity to consumers and identifies all ingredients in the product similar to what is found on the Nutrition Facts and Supplement Facts label.

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[36] *See* 81 Fed. Reg. 38911, "Use of Symbols in Labeling" (Sept. 13, 2016) *available at* https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling ("The Food and Drug Administration (FDA or the Agency) is issuing this final rule revising its medical device and certain biological product labeling regulations to explicitly allow for the optional inclusion of graphical representations of information, or symbols, in labeling (including labels) without adjacent explanatory text (referred to in this document as ''stand-alone symbols'') if certain requirements are met. The final rule also specifies that the use of symbols, accompanied by adjacent explanatory text continues to be permitted. FDA is also revising its prescription device labeling regulations to allow the use of the symbol statement ''Rx only'' . . . in the labeling for prescription devices.")

[37] Roy, R., Alassadi, D. (2021),"Does labelling of healthy foods on menus using symbols promote better choices at the point-of-purchase?", Public Health Nutrition, 24(4), 746–54 (Aug. 28, 2020) *available at* https://www.cambridge.org/core/journals/public-health-nutrition/article/does-labelling-of-healthy-foods-on-menus-using-symbols-promote-better-choices-at-the-pointofpurchase/ACEBE53CFFFE76E2CF63BEBCEE106B94.

[38] *See* Beatriz Franco-Arellano, Lana Vanderlee, *et al.*, "Influence of front-of-pack labelling and regulated nutrition claims on consumers' perceptions of product healthfulness and purchase intentions: A randomized controlled trial", Appetite, v. 149, 104629 (2020) *available at* https://www.sciencedirect.com/science/article/pii/S0195666319309092?via%3Dihub.

25. What precedent exists in foods, dietary supplements, tobacco, and cosmetics for requirements of labeling to present risks to special populations in labeling (e.g., children, pregnant and lactating women, consumers taking certain drugs, etc.)? What amount and type of evidence has been required to support such requirements?

CFCR values the importance of making consumers, especially consumers of vulnerable populations, aware of the risks associated with CBD products.

There are lots of examples of FDA requiring specific warning statements to specific populations for consumer products. For example, FDA requires that all labeling contain allergen disclosures for all major food allergens (e.g., milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, or soybeans).[39] The use of similar allergen warning for CBD products would help ensure risks associated with such allergens are mitigated.

Additionally labeling for food products may also address dietary restrictions for special populations, such as individuals with gluten intolerance or lactose intolerance. In these cases, the labeling should clearly indicate if the product is gluten-free, dairy-free, or suitable for specific dietary needs.

As for tobacco products, the Deeming Rules require that the packages and advertisements of all cigarette tobacco, roll your own ("RYO") tobacco, and covered tobacco products bear an addictiveness warning label statement stating ""WARNING: This product contains nicotine. Nicotine is an addictive chemical".[40] FDA also requires this warning statement to comprise at least 30 percent of each of the principal display panels, be printed in at least 12-point font size and must occupy the greatest possible proportion of the warning label area set aside for the required text, and printed in at least 12-point font size and must occupy the greatest possible proportion of the warning label area set aside for the required text.[41] Though CBD is not psychoactive in the same was as tobacco and therefore not addictive or habit forming, instituting similar font and display requirements in some situations may be beneficial.

For cosmetic products, labeling requirements related to risks to special populations may include warnings for pregnant or nursing women, or restrictions on certain ingredients that may pose risks. The evidence required to support such requirements may include toxicological studies, safety assessments, or epidemiological data demonstrating potential risks or adverse effects.

26. Some suggest requiring labels for CBD products to include "potential THC content." Would THC content be unknown in a particular product? Is there precedent for such a labeling requirement?

While manufactures should know what significant amounts of THC are in a product, when CBD is extracted from hemp, there may be a small amount of THC present that is harder to detect. For broad spectrum products that are sold, it can be assumed by consumers that all THC has been

[39] 21 U.S.C. §§ 321(qq) and 343(w).

[40] 21 C.F.R. § 1143.3(a)(1)).

[41] 21 C.F.R. § 1143.3(a)(2).

removed while keeping the remaining cannabinoids, terpenes, flavonoids, etc., in the product. The amount permissible by law currently is 0.3 percent (3mg/gram) with the same limit on the hemp-derived CBD finished products. This is what is expected as the level of THC in full-spectrum products on the market.

Current lab testing is not reliable enough to determine the precise amount of each of the THC component. Ideally, lab testing will be done by government or non-commercial entities to ensure accuracy and consistency of standards. Because there is potential for inaccuracies and unintentional psychoactivity it is recommended that a label be present showing the potential presence of THC.

27. **How should access to CBD products by children be regulated? For example, would it be appropriate to have an age restriction on the purchase of CBD products? If so, what is an appropriate age limit?**

CFCR would generally support labeling that clearly indicated that CBD products are not to be sold to anyone under the age of 18. While CBD has been shown to be an effective medicine in children with certain seizure disorders, CFCR believes that any use of CBD products by children should be done under the supervision of a physician and thus, we support restriction of sale of CBD products to those over 18.

Nevertheless, CFCR recommends that physicians be allowed to make the recommendation for CBD products up until age 18 without requiring a formal prescription. It is a decision best made between a trained medical professional and the family as to what is right for them. As we learn more through rigorous investigation these guidelines may require adjustment.

28. **What specific additional restrictions should apply to CBD products regarding their appeal to or use by children with regard to marketing, packaging, and labeling? Is there precedent in the food, dietary supplement, tobacco, or cosmetics space for restricting certain product features that would make products appealing to children? Please describe.**

CFCR believes that CBD products should be labeled such that they are intended for adults 18 and older and not for children under the age of 18. Additionally, because these are adult products, CFCR believes that they should not be marketed to children or be designed to mimic children's products.

29. Some suggest requiring packages with multiple servings to be easily divisible into single servings. Does a framework like this exist today for any other product or substance?

Multi-serving/dose packaging exists quite frequently in the food, drug, and cosmetic products. Labeling for these products becomes the educator for consumers, patients, doctors, and pharmacists.[42] FDA has guidelines on the regulations and policies for drug manufacturers in relationship with multi-serving packaging. These guidelines can be found for injectables, for oral solid, and liquid dosing.[43]

Additionally, for inhalation medications for conditions such as asthma, and other lung function conditions, metered dose inhalers are frequently dispensed. These devices contain multi-dose medications that are self-administered through instructions and visual diagrams on packaging as well as insert information.

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[42] *See* FDA, "Frequently Asked Questions about Labeling for Prescription Medicines" (current as of July 2023) available at https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/frequently-asked-questions-about-labeling-prescription-medicines.

[43] *See e.g.* FDA, "Frequently Asked Questions about Labeling for Prescription Medicines" (Oct. 2018) *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/selection-appropriate-package-type-terms-and-recommendations-labeling-injectable-medical-products.

Council For Federal Cannabis Regulation

We thank you for your leadership and recognition of the urgent need for a uniform federal framework for hemp-derived CBD products that prioritizes consumer access and safety and provides certainty to the U.S. market. We look forward to working with you to advance these goals.

Sincerely,

Sheri L. Orlowitz
Founder, Chair of the Board

William A. Garvin
Chair, Science & Regulatory Affairs Committee

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