August 17, 2023

Dear chairs, ranking members, members, and staff of the House Energy & Commerce Committee and the Senate HELP Committee,

Thank you for this opportunity to address you directly regarding CBD regulations. The vacuum caused by a lack of FDA regulations has created a patchwork of state laws that are bad for business and confusing to consumers. Federal regulations are needed immediately to protect consumer safety and small businesses like ours at Cornbread Hemp.

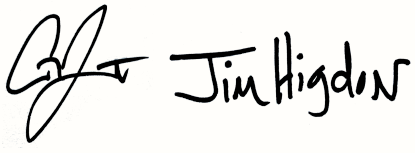
We appreciate these thoughtful and detailed questions. It's clear that members and staff are knowledgeable, curious, and engaged on this issue. Here's a summary of our responses:

- FDA refuses to publish a risk assessment of CBD to determine a safe daily dosage. Why haven't they?
- Other nations have set these CBD limits: Canada: 200mg/day; Australia: 150mg/day; UK: 70mg/day. Why haven't we?
- When defining non-intoxicating CBD products, the definition must include full spectrum CBD products that contain trace amounts of THC up to 0.3% by weight, or 3mg per gram, or 5mg per serving.
- We are concerned about the safety of synthetic intoxicating cannabinoids like delta-8 THC. We hope that Congress, when regulating these cannabinoids, does not over-define these products to include non-intoxicating full spectrum CBD products with trace amounts of THC.
- Despite our concerns with FDA's refusal to issue CBD regulations, we do not believe this is the primary cause of the delta-8 THC boom. Rather, the reason consumers are buying delta-8 THC is due to federal prohibition on non-hemp cannabis. Not to state the obvious, but cannabis prohibition is a threat to consumer safety.

Should Congress decide that CBD products can be regulated as supplements under DSHEA and that adult-use cannabinoids should be regulated more strictly, we urge Congress to understand that non-intoxicating full spectrum CBD products contain trace amounts of naturally occurring delta-9 THC not above 0.3% by weight. These full spectrum CBD products should be regulated as supplements under DSHEA along with THC-free CBD products, as long as CBD remains the dominant cannabinoid.

Thank you again for this opportunity. Our business depends on Congress defining these terms correctly. We are happy to answer any further questions your committees may have.

Yours,



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HOUSE ENERGY & COMMERCE COMMITTEE
SENATE HELP COMMITTEE
AUGUST 17, 2023

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.

Cornbread Hemp has become a market leader by making high quality CBD products at the premium end of the market.

- **Products available:** Cornbread Hemp makes full spectrum CBD products that are USDA certified organic. “Full spectrum” means these products contain a legal amount of naturally occurring delta-9 THC, not more than 0.3%. Full spectrum is the most popular form of CBD with 53% of consumers preferring it, according to Brightfield Group.[1] We make CBD gummies, CBD oils, CBD capsules, CBD topical products, and CBD oil for pets. We do not make inhalation products like flower or vapes; nor does Cornbread Hemp make any products marketed as intoxicating, like delta-8 THC or other novel synthetic cannabinoids. Cornbread Hemp also does not make beverages or food products.
- **Manufacturing practices:** Cornbread Hemp manufactures our own products in our Kentucky-based facility that is certified cGMP and USDA organic.
- **Supply chain:** Cornbread Hemp’s entire supply chain is located within the Commonwealth of Kentucky. In 2023, we are growing 15 acres of hemp on certified organic Kentucky farmland, which we then extract, distill, and turn into finished products in our cGMP facility in Lexington before shipping to customers in all 50 states and US territories from our marketing and fulfillment facility in Louisville. We currently employ 40 full time employees.
- **Marketing and sales:** Cornbread Hemp is primarily a direct-to-consumer business with more than 90% of our revenue coming from ecommerce sales. In 2023, we will grow to more than $20 million in annual revenue.
- **Types of cannabinoids:** Cornbread Hemp products feature CBD as the primary cannabinoid, followed by a legal amount of naturally occurring delta-9 THC, not more than 0.3%. The naturally occurring ratio of CBD:THC is 25:1. Our products also contain a range of minor cannabinoids (CBG, CBN, etc.) that can be found on our third-party lab reports, which are accessible by scanning a QR code on our product packaging.
- **Marketed effects of our products:** Cornbread Hemp does not make drug claims about our products, and we do not market them as being intoxicating. We educate our staff and third-party advocates to speak about our products within the context of structure/function claims under DSHEA. Our customers are looking

for natural supplements to help support their pain, anxiety, and sleep issues. We need Congress to instruct the FDA to allow us to responsibly market our products to consumers in this way.

- **Range of CBD doses:** Cornbread Hemp's ingestible products come in 25mg and 50mg doses of CBD, with 750mg and 1500mg of CBD per bottle. The 25mg CBD per dose products contain 1mg THC; the 50mg CBD per dose products contain 2mg THC. These ratios are naturally occurring in the hemp plant.

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

Since the passage of the 2018 Farm Bill, the growth of the market has stalled due to lack of FDA regulations as individual states pass restrictive regulations in the vacuum of federal action. These individual state regulations have made it nearly impossible for large retailers and social media companies to enter the CBD marketplace because of the compliance headache. At the same time, the passage of the 2018 farm bill caused a massive influx of farmers and producers in the space. Combined with a marketplace that has virtually no retail sales channels or social media marketing, the result was a total implosion of the price of hemp because of the over supply. This hurt farmers, producers, and brands alike.

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

The growth of the CBD market is being suppressed by lack of FDA action. According to projections by the Brightfield Group, the CBD market will grow to $10.3 billion by 2028 with FDA regulations, but to only $5.2 billion in 2028 without FDA regulations.[2]

This market suppression can be seen in the fact that major retailers refuse to carry ingestible CBD products until there is greater clarity from FDA, as well as social media marketing companies refusing to allow CBD on their platforms, thus suppressing the market's full potential.

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.

It does not appear that FDA is being honest with Congress regarding the need for an additional regulatory pathway to regulate CBD. Instead, it appears that FDA is using CBD to achieve a larger goal of controlling the regulations for all cannabis, not just hemp.

FDA has the ability to regulate hemp-derived CBD products that contain THC below 0.3% through existing dietary supplement regulations under DSHEA. But it appears that FDA does not want to regulate CBD in this way because to allow CBD to be regulated under existing dietary supplement regulations does not further their apparent goal of creating a new regulatory pathway to regulate cannabis.

It is our understanding that FDA has the authority to publish a risk assessment of CBD to determine the maximum safe daily dose to be considered a dietary supplement under DSHEA. By the end of 2022, the UK, Canada, and Australia had all established safe daily levels of CBD, but FDA refuses to follow suit.

In April 2023, five FDA employees co-authored a review entitled, “Review of oral toxicity in CBD.” The most relevant passage of this document is the disclaimer that the review “is not a risk assessment and does not seek to identify levels of exposure that may result in adverse effects or levels of exposure that are safe for test animals or for humans.”

For five years, FDA has had the personnel and resources to determine a safe daily dose of CBD, but has refused to do so. Further, FDA employees have published papers raising questions about safe levels of exposure, while refusing to answer those questions, even though FDA has the authority, resources, and time to do so.

Why hasn’t FDA conducted a risk assessment of CBD?

Here are the daily CBD safety levels set by the following nations:

- **CANADA**: 200mg per day, according to Health Canada[3]
- **AUSTRALIA**: 150mg per day, according to the Therapeutic Goods Administration[4]
- **UNITED KINGDOM**: 70mg per day, according to the Food Standards Agency[5]

Scope

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

Congress should define a “CBD Product” as any product in which CBD is the dominant cannabinoid along with a full spectrum of minor cannabinoids, including naturally occurring delta-9 THC up to 0.3% by weight.

Cornbread Hemp makes full spectrum CBD products, which means they contain a modest amount of naturally occurring delta-9 THC. Our strongest product offers 50mg CBD and 2mg THC per serving, which we market as a non-intoxicating supplement.

Our business depends on Congress defining this term correctly. Therefore, we urge Congress to find an acceptable THC threshold to be 5mg per serving. It’s important for

Congress to get this definition correct and to set a non-zero limit of naturally occurring delta-9 THC.

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?

If Congress decides to restrict products such as delta-8 THC or other products marketed as intoxicating, we urge Congress to be mindful that minor levels of naturally occurring THC exist in non-intoxicating CBD products.

Please ensure that any definition of nonintoxicating CBD products include a modest amount of THC, up to 5mg per serving, in a CBD-dominant ratio. Full spectrum CBD products contain up to 0.3% THC, which often amounts to 5mg of THC per serving in a CBD dominant ratio. Further limits on naturally occurring delta 9 THC will make full spectrum CBD products illegal, which would limit the market to CBD isolate only. Full spectrum CBD products are the lifeblood of the industry and the most popular type of CBD product in the market today.

53% of CBD consumers prefer full spectrum CBD products with a modest amount of THC.[1] If THC limits are imposed beyond 0.3% by weight, we believe the entire industry would subsequently implode.

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?

The vast majority of full spectrum CBD products contain 2 to 3 milligrams of THC per serving along with 25 to 50 milligrams of CBD, and 30 servings per container. This means that the majority of full spectrum CBD products contain 25 to 75 milligrams of THC per container. THC limits should not be imposed beyond 0.3% on full spectrum CBD products.

THC limits should be understood in terms of its ratio to CBD. CBD products shall have a CBD-dominant ratio, no less than 10:1 CBD to THC, for example.

But if FDA or Congress decide to set a limit on THC per serving in finished products, we urge Congress to account for the minor amounts of THC in full spectrum CBD products. According to a white paper published by the U.S. Hemp Roundtable, THC remains nonintoxicating up to 5mg per serving.[6]

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

We are concerned about the future of full spectrum CBD products with naturally occurring delta 9 THC as made legal by the 2018 Farm Bill. FDA (or other regulatory agencies like TTB) are well within their authority to restrict the sale of anything still scheduled under the CSA. They should just exclude full spectrum CBD products from any such restriction.

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?

There are multiple examples of dietary supplements that are also prescribed as drugs in higher doses. For example, vitamin C is sold OTC as a supplement, and also prescribed as a drug to prevent and treat scurvy.[7] Zinc is also categorized as both a supplement[8] and a drug.[9]

FDA argues that CBD is different from zinc or vitamin C because CBD was first approved as a drug before it was approved as a supplement and therefore cannot be approved as a supplement. This reasoning appears to makes sense within FDA bureaucracy, but does not make sense outside of it.

For clarity, here's a quick timeline:

- Feb 7, 2014 – Farm Bill signed by President Obama, creating hemp pilot programs.[10]
- 2014 – Charlotte's Web became one of the first CBD oils sold as a supplement in the United States, under the pilot program authorized by the 2014 Farm Bill.[11]
- October 31, 2017 – FDA sent a warning letter to Charlotte's Web for marketing CBD as a supplement.[12]
- June 25, 2018 – FDA approved Epidiolex to market CBD as a drug.[13]
- December 20, 2018 – Farm Bill signed by President Trump, removing CBD from the CSA.[14]

FDA's approval of Epidiolex in the summer of 2018 must be viewed within the context of a burgeoning CBD supplement industry during the same period. It gives the appearance that FDA's approval of Epidiolex as a drug was timed to deny CBD access to dietary supplement regulations. We believe that Congress has the power to mandate that CBD be regulated by FDA as a dietary supplement.

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?

We believe the intoxicating cannabinoid boom is due to federal prohibition of full strength cannabis, not necessarily due to absence of federal CBD regulations. When consumers have safe access to legal cannabis, the market for synthetic delta-8 THC will evaporate. This issue must also be addressed by Congress, but not before considering regulations for non-intoxicating CBD products with up to 5mg of THC per serving in a CBD dominant ratio, like we make at Cornbread Hemp.

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

The public health impact seems to be mostly related to over ingestion of psychoactive compounds that can lead to hospitalizations and negative side effects, as well as the potential for these psychoactive compounds to end up in the hands of children. Full spectrum CBD products do not pose these same public health risks because they are non-psychoactive, despite containing a modest amount of naturally occurring delta-9 THC. .

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

Unsure as we do not sell these products.

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

Congress is well within its power to exclude synthetic cannabinoid products in any regulatory framework currently under discussion. But we urge Congress to understand that CBD products with a modest amount of naturally occurring THC should be included in any definition of nonintoxicating CBD products. We would support Congress' decision to ban synthetic cannabinoids or to limit synthetic cannabinoids to be sold to adults over 21 years old. However, full spectrum CBD products that contain less than 0.3% THC should be regulated as dietary supplements because they are non-psychoactive.

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?

Consumers are interested in topical, inhalable, beverage, and transdermal forms of CBD consumption. We believe that consumers should have the ability to ingest their full spectrum CBD however they would like, including the forms listed above. This would

include hemp flower in raw form. As long as products do not contain synthetically produced cannabinoids, it should not matter which form they come in.

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

Topical CBD products should be less heavily regulated than ingestible or inhalable CBD products because there is little to no danger of negative exposure from a topical CBD product. Consumers want non-ingestible CBD products like CBD balms and CBD lotions, and they should have access to them if they so choose. CBD producers should have the ability to produce these products without over burdensome regulations.

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?

A number of states have restricted retail sales of CBD products, but not necessarily for the purposes of protecting consumer safety.

States with legal cannabis industries (California, Colorado, Minnesota, New York) have restricted CBD products with strict limits on THC per serving and THC per container for the apparent purpose of restricting CBD products to be sold only in legal cannabis dispensaries and not in traditional retail settings, like supplement stores and natural groceries. This does nothing to protect consumers. It only limits access and monopolizes retail sales to one specific sector.

Unregulated retail is often referred to in these conversations in a derogatory way by characterizing non-dispensary retail sales as occurring in gas stations and liquor stores. But please know that natural food groceries, supplement stores, and independent pharmacies make up the vast majority of CBD retail sales, and are a vital and trustworthy source of non-dispensary CBD retail.

States with historically strange liquor laws (Utah, Pennsylvania) also have strange CBD laws, like not being allowed to sell CBD products in stores that also sell alcohol.

We urge Congress to not limit THC in any way other than the 0.3% by dry weight, and a CBD to THC ratio of no less than 10:1.

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

We are unaware of a state to use as an ideal model for federal regulations of full spectrum CBD products with a naturally occurring amount of THC not above 0.3%.

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?

For the sake of brick-and-mortar retailers in states selling CBD products, it is vital that Congress establish a simple set of regulations that all states can follow. Here are the types of retailers we work with in more than 30 states:

- Natural food groceries
- Food co-ops
- Pharmacies
- Supplement stores
- CBD-only stores

All these stores need one set of rules to follow so that good retailers can partner with good product manufacturers. If states are allowed to build upon federal regulations, then retailers in those states will have fewer brands to choose from and the marketplace will never grow to its full potential.

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.

In early 2023, a peer-reviewed journal of the American Society for Clinical Pharmacology and Therapeutics published a review to evaluate evidence of the safety and efficacy of low oral dose CBD. The review looked at 28 studies investigating the safety of CBD, all of which were double-blind and placebo-controlled.[15]

The researchers concluded:

- “CBD appears exceptionally safe, with very few concerns even at the highest dose range considered (300-400mg)”[15]
- “Several high-quality systematic reviews and meta-analyses of CBD safety … generally conclude that CBD has a remarkably safe profile.”[15]
- “The current review found few concerns around safety across the 45 studies analyzed.”[15]

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

The federal government should continue to remove barriers to study hemp and cannabis, while also consulting with scientists doing this research in other developed countries. The federal government should not rely on FDA for cannabis and hemp related research until FDA's motives for capturing regulatory authority over cannabis are fully understood.

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

Honest CBD producers are already going above and beyond normal dietary supplement requirements by including QR codes on CBD product labels that give consumers instant access to batch-specific lab reports and other vital information. However, only 7% of CBD brands conduct appropriate third-party lab tests, according to Leafreport.[16]

Therefore, with clear labeling guidelines and third-party lab reporting requirements, consumers will be safe when consuming full spectrum CBD products with less than 0.3% THC.

The same cannot be said for synthetic cannabinoids like delta-8 THC. Congress is well within its authority to restrict these products as inconsistent with the spirit of the 2018 Farm Bill. Cleaning up the regulations will provide safe access to high quality full spectrum CBD products that are non-intoxicating.

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?

These risks appear to be derived from an FDA-backed messaging campaign that seems to be dishonest at its core. The reason Congress is asking the public this question is because FDA has refused to conduct a risk assessment of CBD, like the ones completed in 2022 by the UK, Canada, and Australia. If FDA was acting in good faith, the FDA itself would have answered this question a year ago.

Available evidence suggests that 300mg CBD is a safe daily dose. In a systematic review and meta-analysis on cannabidiol-associated hepatotoxitcity published in 2023, researchers from the US and Canada looked at more than 15,000 humans using CBD and found zero cases of liver toxicity in adults taking less than 300mg CBD per day.[17] Therefore, Congress should feel comfortable instructing FDA to set a daily limit on CBD to 300mg per day until FDA conducts its own risk assessment, which is long overdue.

Our peer nations have answered this question by capping the daily dose of CBD in the following amounts:

- Canada: 200 mg/day[3]

- Australia: 150 mg/day[4]
- United Kingdom: 70 mg/day[5]

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?

This is a simple question of dosage. The dosage for Epidiolex is 3,000mg per day, while CBD products sold as supplements might be offered in packages designed to offer 3,000mg per month.

The fact that FDA refuses to acknowledge data submitted by CBD companies on the safety of their products, while they continue to release studies of rodents at Epidiolex-equivalent dosing levels, is continued evidence that FDA is not acting in good faith when refusing to regulate CBD under existing regulatory authority.

FDA intentionally focuses on data on rodents that are given huge doses of CBD more than ten times higher than the dosage recommended for CBD as a dietary supplement for humans. Then, they use this data on high doses of CBD to say that low-dose CBD is unsafe.

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?

Yes, there needs to be limits set in order to have a system where CBD dietary supplements exist alongside CBD drugs like Epidiolex. FDA has damaged its credibility in this process and is unlikely to set the CBD dosage limit at a level that is based on available data in good faith.

As we understand it, the CBD dosage limit could be determined by an FDA risk assessment, which the FDA refuses to conduct. Therefore, Congress will need to work with the honest CBD producers who are making resources available in order to set these limits in a safe, responsible way that is good for consumers and producers alike.

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

The amount should be determined by following the work of existing research and standards set by our peer nations.

- 300mg per day, if we follow this review of 15,000 adult humans that found zero cases of liver damage in adults that took less than 300mg CBD per day.[17]

- 200mg per day, if we follow the guidance set by Health Canada[3]
- 150mg per day, if we follow the guidance set by Australia's Therapeutic Goods Administration[4]
- 70mg per day, if we follow the guidance set by the UK's Food Standards Agency[5]

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

The limit should be both per serving and per package, but these limits are imperative to get correct in order to preserve the CBD marketplace without damaging it. We believe that 3,000mg total CBD per container is a safe and reasonable limit for a monthly CBD consumer, while 200mg is an appropriate limit on a per day basis – similar to the level set by Health Canada. Setting a daily limit prevents brands from being cute about serving size and the total CBD per container.

Packaging should have CBD and THC dosage per serving and per package. Other cannabinoid content can be accessed via QR code on packaging that points to lab tests.

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?

Yes. As soon as FDA conducts a long overdue risk assessment to determine a safe level of daily CBD dosing and nonintoxicating THC exposure. However, as we referenced above, we are not convinced that FDA can be trusted with this. Congress may need to set these limits so that FDA does not undermine the industry with arbitrarily strict limits that would put companies like Cornbread Hemp out of business.

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

The experience of states is a mess. Where states tend to misstep is not the restriction of the amount of CBD per package, but in restrictions to naturally occurring THC. Minnesota's cap of 50mg THC per package and New York's cap of 1mg THC per serving and 10mg per package makes it difficult for full spectrum CBD brands who make non-psychoactive products to serve retailers in those states without uniform guidelines. This is why it is essential for Congress to act in order to create a marketplace that exists in all states.

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.)?

Cornbread Hemp does not make products that contain caffeine or melatonin, so we have no experience or customer insights into this issue.

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?

None, to our knowledge.

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

None, to our knowledge.

Quality

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

This framework already exists - DSHEA. Regulate CBD products as dietary supplements and require producers to follow these same requirements. This will allow Congress and FDA to establish a clear set of standards for CBD manufacturing that can ensure consumer safety.

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

As similarly as possible. Honest producers like Cornbread Hemp are already GMP certified and would welcome the requirement.

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

Yes, with the addition of third-party lab reports that include tests not only for potency, but for contaminants like pesticides, residual solvents, and heavy metals, as well.

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?

CBD products should be tested by third-party labs with the lab reports available for consumers via QR code on product packaging. The batch number for that specific product and batch should be printed somewhere on the packaging of the product. This batch number printed on the product should match the batch number on the third-party lab report so ensure that every batch is being tested.

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.

CBD product manufacturers should be permitted to make structure/function claims as if the CBD products are dietary supplements as regulated under DSHEA. CBD consumers are using CBD products for three primary reasons: to relieve aches and pains, reduce stress, and to support a healthy sleep cycle.

CBD manufacturers want to be able to appropriately market their products to consumers dealing with minor pain, anxiety, and sleep issues without making overt drug claims. This is achievable using structure/function claims as permitted under DSHEA.

When properly regulated as a dietary supplement under DSHEA, appropriate structure/function claims made by responsible CBD manufactures could include:

- Relieves pain caused by exercise-induced inflammation
- Supports good mental health
- Supports a healthy sleep cycle

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?

Don't know of any.

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?

We believe this is unnecessary and overburdensome, and will only confuse consumers. We don't need to reinvent the wheel. The Supplement Facts Panel works just fine.

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?

Not our expertise.

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?

THC content should be known in any CBD product. A product that contains THC should be labeled as containing THC and with the exact milligram per serving, even when less than 0.3% by dry weight. Responsible CBD brands like Cornbread Hemp are already doing this.

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?

Due to the non-psychoactive nature of CBD, we believe there is little evidence to suspect underage use or abuse of CBD products that would justify an age limit. A larger concern is accidental ingestion of CBD products by children, for which we support child-safe packaging on all ingestible CBD products. We do not believe that child-safe packaging is necessary for topical products as they pose significantly lower risk of accidental ingestion. We do not believe age restrictions are necessary for full spectrum CBD products because they are non-psychoactive.

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.

CBD products should not be marketed to children, but we don't believe that an age limit for purchase is necessary for non-psychoactive full spectrum CBD 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?

Cornbread Hemp does not make products to which this question would apply.

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