Aug 18, 2023

Hon. Cathy McMorris Rodgers
Chairperson, U.S. House Committee on Energy and Commerce

Hon. Bill Cassidy, M.D.
Ranking Member, U.S. Senate Committee on Health, Education, Labor and Pensions

Hon. Frank Pallone, Jr.
Ranking Member, U.S. House Committee on Energy and Commerce

Hon. Bernard Sanders
Chairperson, U.S. Senate Committee on Health, Education, Labor and Pensions

VIA EMAIL: CBD@mail.house.gov, CBD@mail.senate.gov

Dear Rep. McMorris Rodgers; Sen. Cassidy, M.D.; Rep. Pallone, Jr.; Sen. Sanders:

The Hemp Beverage Alliance is honored to provide the following response to your inquiry regarding a legislative approach to the regulation of CBD products.

The Alliance includes more than 70 hemp brands, service providers and ingredient manufacturers in the hemp beverage industry. Together, we are dedicated to creating a marketplace that is transparent, sustainable, and provides consumers with the highest quality hemp-infused drinks.

Our members strongly believe the following tenets should guide regulatory decisions regarding hemp beverages:

- Safety – The safety of the consumer is paramount and should be the driving force in the industry.
- Age limit – Hemp beverages are adult beverages and should be labeled and sold accordingly.
- Serving size – Cannabinoid levels should be safe, effective, and provide value to the consumer.
- Labeling – Clear labeling is necessary to empower the consumer and build credibility for the industry.
- Regulatory clarity – Regulations are necessary and should be thoughtful, concise, and support consumer safety and industry growth.
- Marketplace consistency – In lieu of federal action, state governments should work together to develop guidelines that are consistent across state lines.

The Hemp Beverage Alliance applauds Congress' efforts to thoughtfully regulate CBD products. The current disconnection between the legalization of hemp in 2018 and the lack of regulation five years later has created frustration, economic pain and confusion for consumers, retailers, distributors, producers, and farmers throughout the country.

However, CBD is not the only hemp derivative that was legalized under the 2018 Agriculture Improvement Act ("the 2018 Farm Bill"). Indeed, the 2018 Farm Bill specifically defines hemp as:

> "[...] the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing

or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." (Sec. 297a)

While CBD is a valuable cannabinoid with tremendous potential, it is the low-dose, hemp-derived delta-9 tetrahydrocannabinol (THC) and full spectrum products that truly are in demand by the American consumer.

Since its legalization in the 2018 Farm Bill, low-dose hemp-derived full spectrum beverages have been embraced by adult consumers seeking relaxation and relief. Recognizing this demand, hundreds of companies have developed tinctures, topicals and edibles that include THC derived from legal hemp. More recently, due to advancements in technology, entrepreneurs and established companies have been able to incorporate hemp-derived THC into beverages.

This is where the hemp marketplace is poised for significant growth, and this is where Congress has the opportunity to support farmers, small businesses, veterans, seniors, and countless others who benefit from the production, distribution, sale and consumption of regulated, hemp-derived products.

The Hemp Beverage Alliance encourages Congress to:

- Delineate different pathways for the regulation of CBD and THC beverages:
    - CBD is a non-impairing compound and should be allowed to be incorporated into food and dietary supplements and be regulated by the Food and Drug Administration (FDA)
    - THC has the potential to impair. Beverages containing potentially impairing levels of THC legally derived from hemp should be regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB).

- Appropriate funding to TTB to develop a regulatory framework for beverages infused with THC derived from legal hemp.

- Appropriate funding to TTB to develop programs to educate distributors, retailers, state regulators and the general public about hemp-derived THC beverages. Educational programs should emphasize safety, responsible consumption, and the restriction of products to adults aged 21 years or older.

- Develop a framework to tax hemp-derived THC beverages in a manner similar to alcohol. This will benefit tax payers and provide funding for market regulation and oversight.

- Encourage uniformity in labeling requirements among the states. This will empower consumers and free beverage companies from onerous, state-by-state requirements.

- Work with the hemp beverage industry to create a sensible, thriving, safe industry. We share Congress' goals to help America's farmers and small businesses, as well as other businesses that have been economically impacted by COVID and other market forces. Together, we can create a strong hemp beverage marketplace that protects children, creates jobs, stimulates local economies, and provides adult consumers with products they enjoy and demand.

Whether it's called cannabis, hemp, or marihuana, the American public clearly has embraced cannabis sativa L. and the compounds that can be derived from it. We hope Congress will recognize that criminalization of the plant is no longer a politically, ethically, or economically viable policy. A regulatory pathway must be enacted quickly to create a thriving marketplace that is safe and sustainable.

We welcome the opportunity to discuss the Alliance's position with you and your staff, and stand ready to support any legislation that creates a safe, viable pathway for the beverage industry to grow.

Sincerely,

Christopher Lackner
Executive Director
Hemp Beverage Alliance

RESPONSES TO RFI QUESTIONS

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.

Hemp beverages are seltzers, sodas, mocktails, coffees, teas, and other drinks that contain an infusion of hemp-derived cannabinoids, terpenes, and/or fibers. Common cannabinoids include CBD and THC, but other "minor cannabinoids" can also be incorporated.

In terms of cannabinoid levels and ratios between THC and CBD, each product in the marketplace is unique. The Hemp Beverage Alliance suggests beverages should contain no more than 10 mg of hemp-derived THC per serving and no more than 30 mg of CBD per serving. It should be noted that Minnesota law allows 5 mg of THC per serving and 10 mg of THC per container.

Hemp beverages are manufactured in facilities where other beverages are made such as breweries and co-packing facilities. These facilities adhere to current Good Manufacturing Practice (cGMP) regulations, OSHA regulations, and all other regulations required of food and beverage manufacturing facilities.

Hemp Beverage Alliance members source their cannabinoids from reputable companies. These companies test every batch of their products before providing them to the beverage manufacturer. Testing confirms that the cannabinoid levels are accurate and that there is no yeast, mold, heavy metals, or other contaminants in the product. Cannabinoids are shipped to manufacturers in secure containers.

The introduction of the cannabinoids into the beverage is a rather simple process. Usually this involves pouring the cannabinoid mixture (a liquid or a powder emulsion) into the tank along with the flavors, sweeteners, preservatives and other ingredients.

Hemp beverages generally are packaged in aluminum cans and glass bottles, with volumes ranging from six ounces to 20 ounces, with 12 ounces being the most common.

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

The passage of the 2018 Farm Bill coincided with a consumer trend away from alcohol consumption. As more Americans reevaluate their relationship with beer, wine and spirits, hemp-infused beverages are increasingly becoming their drink of choice.

Hemp beverages started to boom in 2022. Adult consumers finally had a functional alternative to alcohol. The dwindling beer industry had a new offering to manufacture and sell. Struggling small retailers had a product that was in high demand. Hemp farmers could finally sell biomass to meet the demand. Veterans and others seeking relief and recreation found a product that was safe, approachable, socially acceptable and effective.

In 2023, larger retailers, distributors and manufacturers began to recognize the demand and opportunity to be found in hemp beverages. Everything from supply chains, financial investments, retail agreements, and marketing budgets is set up to create a safe and thriving marketplace. All that remains is regulatory clarity at the federal level.

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

Hemp beverages are in strong demand. However, no industry can operate successfully with a 50-state patchwork of conflicting laws.

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.

Asking the FDA to implement a novel regulatory protocol is unnecessary for hemp beverages. TTB already provides a robust precedent to ensure quality, safety, taxation, chain-of-custody oversight and fair competition of adult-use beverages.

Scope

5. How should CBD and/or cannabinoid-containing hemp products be defined? What compounds should be included and excluded from a regulatory framework? 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? 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? Should FDA regulate the manufacture and sale of "semisynthetic derivatives," or "biosynthetic cannabinoids," which are still scheduled under the CSA?

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Cannabinoid-containing hemp products should be defined just as they Farm Bill defines hemp: "[...] the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." (Sec. 297a)

Congress should direct TTB to regulate hemp beverages. With TTB's oversight, taxation, and age-restriction programs, hemp-derived THC beverages should be available for sale in conventional retail stores and on-premise alcohol locations in a manner similar to beer.

TTB should establish a standard for serving size and measurement to empower and protect consumers and provide consistency across the country. The Hemp Beverage Alliances suggests hemp-derived THC beverages should be no more than 10 mg per container.

Neither Congress nor FDA should criminalize semisynthetic derivatives or "biosynthetic" cannabinoids. There is no understandable definition of synthetic or biosynthetic and these distinctions are confusing and not enforceable. The effect of the product and its intended use are what matters. If these products have the same effect on the human body, they should be regulated in the same way.

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?

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? What is the public health impact of these novel compounds? How have FDA and state regulators enforced against products containing these compounds? How should Congress consider the inclusion of these products in a regulatory framework for cannabinoid hemp products, if at all?

Whether a compound is synthetic or not (and there is no definition of synthetic) is irrelevant to public health. If a compound is inherently dangerous at a certain level, then it should not be on the market. If a product is on the market and causing serious adverse health consequences or death, it should be taken off the market.

If the compound is causing harm, then FDA and states have acted. This is the correct approach. These compounds are no different than other compounds and should be on the market after the manufacturer determines they are safe.

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.). For which non-ingestible routes of administration are consumers interested in consuming CBD products? How should a regulatory framework for cannabinoid products account for non-ingestible routes of administration?

This question is not applicable to the hemp beverage industry.

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

The Hemp Beverage Alliance strongly supports legislation that emulates recent laws enacted in the state of Minnesota. Highlights of the Minnesota law include:

- Lower-potency hemp edible products or beverages may only be sold in the state of Minnesota to people age 21 or older. The retailer must verify the purchaser's age through a valid state-issued driver's license or identification card, Tribal identification card, passport, instructional permit, or Canadian driver's license.
- Containers may not contain more than 2 servings and no more than 5 mg of delta-9 THC per serving and 10 mg total THC.
- Synthetic cannabinoids or other artificially derived cannabinoids (other than delta-8 or delta-9 THC) are prohibited. THC-P, THC-O, and HHC are prohibited.
- The product cannot contain any ingredient not approved by the U.S. Food and Drug Administration (FDA) for use in food, with the exception of hemp-derived cannabinoids.
- The product cannot be a commercially available candy or snack food item where CBD or hemp THC has been applied to or added.
- The product must not be packaged in a container that includes a statement, artwork, or design that could reasonably mislead any person to believe that the package contains anything other than an edible cannabinoid product.
- The product cannot be contaminated or have more than trace amounts of mold, residual solvents or other catalysts from processing, pesticides, fertilizers, or heavy metals.

In addition, the Hemp Beverage Alliance suggests adoption of ASTM's Cannabinoid Labeling Standards (D8449). These standards include important consumer safety requirements such as

- Cannabinoid levels on front panel
- FDA disclaimer
- Medical and pregnancy warning
- Intoxicating Cannabinoid Universal Symbol
- Link to Certificate of Analysis (URL or QR code)

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 hemp beverage products, the model should be the TTB approach to state/federal jurisdiction.

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.

The hemp beverage industry uses CBD and THC as the main cannabinoids. Congress and FDA have access to extensive research on the safety of these compounds.

Hemp beverages use very low levels of these cannabinoids by comparison to the level of the drug approval of Epidiolex.

Hemp beverages have been on the market in the United States for well over a decade without significant safety incidents and should be deemed safe through common experience.

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

We encourage the federal government to continue to research the many benefits of hemp. The more research, the better the understanding and appreciation of these mighty molecules.

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

TTB does an excellent job of balancing consumer safety with consumer access. Rather than create a new framework, the Hemp Beverage Alliance strongly recommends regulating hemp-derived THC beverages through that agency, using the proven precedents of ethanol regulation.

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?

Multiple studies have been performed and reviewed that prove, unequivocally, that CBD in low doses should be GRAS.

For hemp beverages, the health risk comes when the consumer does not know the level of cannabinoids in a product prior to consumption. That is why we recommend clear labeling and consistency of products throughout the country.

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?

Multiple studies have been performed and reviewed that prove, unequivocally, that CBD in low doses should be GRAS.

Drug approvals require clinical (human) data, but food and supplement approvals (self-determined studies allowed by law) do not require clinical data. Food and supplements can rely on publicly available research supplemented if necessary by rodent studies. Alternatively, for food and supplements, products can be deemed as safe based on long-term use.

16. Should there be limits on the amount of CBD in foods, dietary supplements, tobacco, or cosmetics? Should Congress or FDA set such limits, recognizing the time it can take to complete the legislative process and the regulatory process at FDA? How should that amount be determined? What should the amount be? Should such limits be applied on the amount per serving, and/or per package? 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? How should the experience of states inform the setting of limits on amounts of CBD in products?

Hemp beverages should be regulated by TTB. As a starting point for discussion, we suggest limits that adhere to Minnesota law:

- Containers may not contain more than 2 servings and no more than 5 mg of delta-9 THC per serving and 10 mg total THC.
- Synthetic cannabinoids or other artificially derived cannabinoids (other than delta-8 or delta-9 THC) are prohibited. THC-P, THC-O, and HHC are prohibited.

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.)?

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?

Contrary to the framing of the question, FDA has used regulatory authority to override the drug preclusion act in interest of consumer access and markets for safe products. For example, FDA recently decided to use "enforcement discretion" on NAC based on industry pushback.

In short, there is no precedent for FDA to restrict hemp products in the way they have, and this further highlights the agency's reluctance to manage hemp products, which is why we feel TTB is the correct agency for hemp beverages.

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

Quality

20. How should Congress create an FDA-implemented framework to ensure that manufacturers provide appropriate consumer protections and quality controls? How should such a framework compare to the current Good Manufacturing Practice (GMP) requirements that apply to food,

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

Congress should direct TTB to regulate hemp-infused beverage production in a way that is similar to their regulation of alcohol production.

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?

Congress should direct TTB to regulate hemp-infused beverage production in a way that is similar to their regulation of alcohol production.

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.

Hemp beverages should be allowed to make claims regarding health profile compared to alcohol, that hemp beverages do not cause hangovers. Further, hemp beverages should be able to make structure and function claims.

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?

The Hemp Beverage Alliance supports the use of ASTM iconography to empower consumers in their decision making.

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?

Consumers understand and recognize current labeling practices. New labels would only confuse.

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?

The Alliance supports clear labeling on beverages to empower consumers to make informed choices, and as such, we recommend adoption of ASTM's Cannabinoid Labeling Standards (D8449) to provide customer safety through consistency in labeling and truth in advertising.

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?

The Alliance supports clear labeling on beverages to empower consumers to make informed choices. This includes listing THC content.

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?

In the case of hemp beverages that contain potentially impairing levels of THC, we advocate for a 21+ requirement.

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.

The Hemp Beverage Alliance supports labeling restrictions that are consistent with alcohol. We oppose restrictions that are not founded in credible research.

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?

Yes. This exists in food, beverages, and dietary supplements currently. So long as the average adult is able to follow the instructions and reach the desired outcome, there is no reason to have overly onerous requirements for multi-serving units that do not exist in other categories of consumables.

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