

**Congress of the United States**  
Washington, DC 20515

July 27, 2023

To Interested Parties:

Cannabidiol (CBD) is a compound derived from the *Cannabis Sativa* plant. It is a non-psychoactive cannabinoid that has been promoted for its use relative to a number of health conditions. Public Law 115-334, the Agriculture Improvement Act of 2018 (“the 2018 Farm Bill”) expanded the definition of hemp to include “all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers,” containing no more than 0.3% concentration of delta-9 THC. It also removed hemp from the definition of marijuana under the Controlled Substances Act (CSA), descheduling hemp-derived CBD.<sup>1</sup> However, the 2018 Farm Bill preserved the authority of the Food and Drug Administration (FDA) to oversee CBD in FDA-regulated products.<sup>2</sup>

Since the Farm Bill was enacted, FDA has maintained that hemp-derived CBD may not be marketed as a food additive or dietary supplement. Citing a provision included in the 1994 Dietary Supplement Health and Education Act (DSHEA) that prohibits articles from being marketed as a food or dietary supplement if they are studied or approved as a drug (the “exclusionary clause”), FDA asserts that it cannot permit hemp-derived CBD food and dietary supplement products for public consumption because there is currently an approved drug with CBD as an active ingredient on the market. However, even if the exclusionary clause did not apply, FDA has indicated that CBD would not meet the relevant statutory requirements for food or dietary supplement due to safety concerns.

Since hemp was descheduled five years ago, consumers, manufacturers, and policymakers have sought clarity regarding the legal status of CBD. Farmers, food and beverage groups, and state regulators have shared their policy priorities with Congress. However, questions remain about the best way to provide a legal pathway to market for CBD products.

**Purpose of the Request for Information**

In January 2023, FDA announced that it would like to work with Congress to craft a legislative approach to the regulation of CBD products. We are assessing the potential for a regulatory pathway for hemp-derived CBD products that prioritizes consumer safety and provides certainty to the U.S. market. We look forward to working with interested stakeholders on this process, and we ask for written responses on the following inquiries submitted to [CBD@mail.house.gov](mailto:CBD@mail.house.gov) and [CBD@help.senate.gov](mailto:CBD@help.senate.gov) by August 18. Please provide all data and primary source information, as is feasible, in answering the questions below.

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<sup>1</sup> P.L. 115-334 §10113.

<sup>2</sup> 7 U.S.C. § 1639r.

### 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.
2. How has the market changed since the passage of the 2018 Farm Bill?
3. How is the lack of national standards for CBD products affecting the market?

### 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.

### Scope

5. How should CBD and/or cannabinoid-containing hemp products be defined? What compounds should be included and excluded from a regulatory framework?
  - 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?
  - 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?
  - c. Should FDA regulate the manufacture and sale of "semisynthetic derivatives," or "biosynthetic cannabinoids," which are still scheduled under the CSA?
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?
  - a. What is the public health impact of these novel compounds?
  - b. How have FDA and state regulators enforced against products containing these compounds?
  - c. How should Congress consider the inclusion of these products in a regulatory framework for cannabinoid hemp products, if at all?
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?
  - b. How should a regulatory framework for cannabinoid products account for non-ingestible routes of administration?

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

#### 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.
12. What actions, if any, should the Federal government take to better understand the potential benefits or harms of CBD products and other cannabinoids?
13. How should a new framework for CBD products balance consumer safety with consumer access?
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?

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

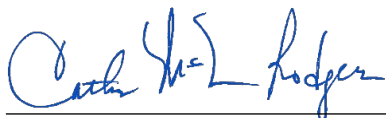
### Quality

20. How should Congress create an FDA-implemented framework to ensure that manufacturers provide appropriate consumer protections and quality controls?
  - a. How should such a framework compare to the current Good Manufacturing Practice (GMP) requirements that apply to food, dietary supplements, and cosmetics?
  - b. Are those food, dietary supplement, and cosmetics GMP frameworks adequate for regulating quality in CBD? Why or why not?
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?

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.
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?
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?
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?
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?
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?
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.
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?

Sincerely,



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Cathy McMorris Rodgers  
Chair  
U.S. House Committee on Energy and Commerce



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

*Frank Pallone, Jr.*

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Ranking Member

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Bernard Sanders

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Education, Labor, and Pensions