



August 18, 2023

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

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

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

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

Dear Chairs Sanders and McMorris Rodgers, and Ranking Members Cassidy and Pallone:

The Center for Science in the Public Interest submits this comment in response to the [July 2023 Congressional Request for Information](#) regarding the potential for a regulatory pathway for hemp-derived cannabidiol (CBD) products.

For almost five years, the US Food and Drug Administration (FDA) has repeatedly warned that foods and supplements containing CBD are illegal under FDA's exclusion clause.¹ However, their warnings and occasional enforcement actions have been unable to stop or safely regulate the now \$5 billion CBD market.² This Request for Information is therefore timely, especially as FDA stated this year that it will work with "Congress to develop a cross-agency strategy for the

¹US Food and Drug Administration (FDA). *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*. July 5, 2023. <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>. Accessed August 15, 2023.

² *Id.*; FDA. *A New Way Forward for Cannabidiol (CBD) and Other Hemp Products*. Slide 4. May 25, 2023. <https://www.fda.gov/media/168778/download?attachment>. Accessed August 15, 2023.

regulation of [CBD] products.”³ Congress must take swift action to provide FDA with the necessary funding and authorities to address the risks of CBD before this underregulated and rapidly growing market brings additional harm to consumers.

Given FDA’s public health mission and existing expertise in products marketed as food, dietary supplements, and drugs, we urge Congress to provide the agency with additional authority and funding to oversee the safety and marketing of CBD products. CSPI does not currently take a position on whether CBD products should be regulated as a subset of foods or require an entirely distinct regulatory pathway. However, given the gaps and challenges that currently exist in FDA’s authority over food and dietary supplements, the agency clearly cannot simply regulate these products using its existing authority over food or supplements. Accordingly, this letter identifies gaps and challenges in FDA’s existing food and dietary supplements authorities and highlights the authorities that should be conferred to the agency in order to safely regulate CBD products.

I. Current Regulatory Framework is Largely Ignored by the CBD Industry

The 2018 Farm Bill decriminalized and redefined hemp as the plant, *Cannabis sativa L.*, and anything derived from it with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis.⁴

Despite hemp-derived CBD falling into the definition of hemp, FDA has maintained that CBD cannot legally be added to foods or dietary supplements because it is the active ingredient in the approved drug, Epidiolex.⁵ The Food, Drug, and Cosmetic Act’s exclusion clause for supplements and list of prohibited acts for foods both prohibit approved active drug ingredients from being included as an ingredient in such products.⁶ The purpose of this policy is twofold: it prevents many pharmacologically active and potentially dangerous ingredients from entering our foods and supplements and incentivizes new drug development to treat diseases.

FDA has the authority to waive the drug exclusion rule for particular ingredients by regulation but has declined to do so for CBD due to concerns around safety.⁷ In January 2023, FDA rejected industry petitions requesting that FDA use its rulemaking authority to override the exclusion clause and allow CBD in dietary supplements.⁸ The rejection letter reaffirmed the

³ 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*. January 26, 2023. <https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol>. Accessed August 9, 2023.

⁴ Pub. L. 115–334, title XII, §12619(a), Dec. 20, 2018, 132 Stat. 5018; 7 USC U.S.C. § 1639o(1)

⁵ FDA. *Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency’s regulation of products containing cannabis and cannabis-derived compounds*. December 20, 2018. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys>. Accessed August 8, 2023.

⁶ *Id.*; 21 U.S.C. § 331(ll); 21 U.S.C. § 321(ff)(3)(B).

⁷ 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*. January 26, 2023. <https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol>. Accessed August 9, 2023.

⁸ *Id.*

agency's position that CBD cannot be safely regulated as an ingredient in dietary supplements.⁹ FDA also declared that CBD is not generally recognized as safe (GRAS) for foods or dietary supplements.¹⁰ Therefore, even if the exclusion clauses were overridden by Congress or FDA, companies would still have to seek premarket approval for different uses of CBD to foods and dietary supplements.

However, despite the federal ban on including CBD in foods and dietary supplements, the CBD industry has largely ignored FDA rules. Manufacturers of CBD edibles, many of which are small, fly-by-night companies lacking substantial experience in food manufacturing, continue to market CBD edibles, even as FDA has issued repeated warnings that CBD is an illegal food and dietary supplement ingredient. There is no reason to believe that FDA's 2023 petition rejection will curtail the \$5 billion CBD marketplace or make it any safer. CBD companies will continue to operate outside of FDA's oversight, unless Congress creates a regulatory framework that protects consumers against fraudulent and unsafe CBD products.

II. CBD Safety Concerns

As a pharmacologically active chemical, CBD carries inherent risks. In its 2023 petition rejection, FDA cited to “studies show[ing] possible harm to the male reproductive system, including testicular atrophy; harm to the liver; and interactions with certain medications.”¹¹ The agency was also concerned with its effects on certain vulnerable populations, such as children and those who are pregnant.¹²

Similarly, FDA's 2019 literature review on the safety of CBD in humans found that ingested CBD had risks of somnolence (18%; 3% severe), central nervous system adverse reactions such as agitation and sedation (1-4%), decreased appetite (16%), diarrhea (9%), and decreased weight (3%).¹³

Notably, FDA's concerns are based on studies of adverse effects from CBD drugs. While the agency could set lower limits on the dosages of CBD permitted in food and dietary supplements, FDA had “not found adequate evidence to determine how much CBD can be consumed, and for how long, before causing harm.”¹⁴

⁹ FDA. *Response Letter from FDA CFSAN to Consumer Healthcare Products Association*. January 26, 2023. <https://www.regulations.gov/document/FDA-2019-P-5394-0004>. Accessed August 9, 2023.

¹⁰FDA. *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*. July 5, 2023. <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>. Accessed August 15, 2023.

¹¹ FDA. *Response Letter from FDA CFSAN to Consumer Healthcare Products Association*. January 26, 2023. <https://www.regulations.gov/document/FDA-2019-P-5394-0004>. Accessed August 9, 2023.

¹² 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*. January 26, 2023. <https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol>. Accessed August 9, 2023.

¹³ FDA. *Safety of CBD in Humans – A Literature Review*. December 12, 2019. <https://www.fda.gov/media/152317/download>. Accessed August 9, 2023.

¹⁴ 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*. January 26, 2023. <https://www.fda.gov/news->

A new CBD framework for foods and supplements must create safeguards to mitigate the risks inherent to the chemical itself while still encouraging the development of approved CBD drugs.

III. New Authority and Resources are Needed to Ensure the Safety of CBD Products

FDA's inability to control the explosive growth of illegal CBD products has created an underregulated market. This has led to CBD products that are:

- **Mislabeled with respect to their CBD quantities:** After testing 147 CBD products, FDA found that more than half contained CBD in amounts that differed from what their labels indicated.¹⁵ Of the 102 products that indicated a specific amount of CBD, 18 products (18 percent) contained less than 80% of the amount of CBD indicated, 46 products (45 percent) contained CBD within +/-20 percent of the amount indicated, and 38 products (37 percent) contained more than 120 percent of the amount of CBD indicated.¹⁶ For the nine samples that did not contain CBD, seven either did not indicate CBD or clearly indicated “zero CBD” on the label.¹⁷ Two products that listed CBD on the label were not found to contain CBD.¹⁸
- **Adulterated:** CBD products have been found to contain ingredients not listed on product labels, including synthetic cannabinoids and dangerous contaminants.¹⁹ In one study, 20% of CBD products were found to be adulterated with THC, some containing amounts sufficient to produce intoxication or impairment, especially among children.²⁰ A May 2019 study by CBS News and Ellipse Analytics found that 70 percent of hemp-derived CBD products were “highly contaminated” with metals like lead and arsenic, herbicides like glyphosate, and “a host of other contaminants including pesticides, BPA

[events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol](#). Accessed August 9, 2023.

¹⁵ FDA. *Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent That Products are Mislabeled or Adulterated*. 2020. https://hempindustrydaily.com/wp-content/uploads/2020/07/CBD-Marketplace-Sampling_RTC_FY20_Final.pdf. Accessed December 2, 2020.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *E.g.*, Poklis JL, et al. The Unexpected Identification of the Cannabimimetic, 5F-ADB, and Dextromethorphan in Commercially Available Cannabidiol E-Liquids. *Forensic Sci Intl*. 2019;294:e25-227; Bonn-Miller MO, et al. Labeling Accuracy of Cannabidiol Extracts Sold Online. *JAMA*. 2017;318(17):1708-1709; FDA. *Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent That Products are Mislabeled or Adulterated*. 2020. https://hempindustrydaily.com/wp-content/uploads/2020/07/CBD-Marketplace-Sampling_RTC_FY20_Final.pdf. Accessed December 2, 2020.

²⁰ Bonn-Miller MO, Loflin MJE, Thomas BF, Marcu JP, Hyke T, Vandrey R. Labeling Accuracy of Cannabidiol Extracts Sold Online. *JAMA*. 2017 Nov 7;318(17):1708-1709. doi: 10.1001/jama.2017.11909. PMID: 29114823; PMCID: PMC5818782.

and toxic mold.”²¹ Cannabis products in general, not just CBD products, have been found to have a history of contamination of heavy metals;²² pathogens, such as mold, Salmonella, or E. Coli;²³ and pesticides²⁴

- **Include illegal disease claims:** A slew of companies have already illegally advertised CBD products for treating and preventing diseases,²⁵ such as, COVID-19,²⁶ opioid addiction,²⁷ teething and ear pain in infants,²⁸ autism,²⁹ ADHD,³⁰ Parkinson’s and Alzheimer’s disease,³¹ breast cancer,³² diabetes,³³ and pain relief.³⁴ FDA has not approved CBD for any of these conditions.
- **Inappropriately marketed to vulnerable populations such as children and pregnant people:** CBD supplements are marketed for children’s use³⁵ and as treatments for

²¹ CBS Austin. The Risk of Contaminants and False Labeling in the Exploding CBD Industry. May 15, 2019. <https://cbsaustin.com/news/nation-world/the-risk-of-contaminants-and-false-labeling-in-the-exploding-cbd-industry> Accessed September 19, 2019.

²² E.g., Nascarella MA. Ensuring Safe Patient Access to Medical Marijuana Products in Massachusetts. Massachusetts Department of Public Health. <https://mass-cannabis-control.com/wp-content/uploads/2017/12/NASCARELLACCCAB110317.pdf>. Accessed August 17, 2023.

²³ Hughes, T. Tough testing keeps some pot off Washington shelves. USA Today. December 18, 2014. <https://www.usatoday.com/story/news/nation/2014/12/18/washington-state-marijuana/20588285/>. Accessed July 15, 2019.

²⁴ Blood MR. Big safety testing failure rate for California pot products. AP News. September 11, 2018. <https://apnews.com/2cb04323f9074c1ca28001693f6e2a8a>. Accessed July 12, 2019.

²⁵ FDA. *FDA News Release: FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns*. November 25, 2019. <https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details>. Accessed December 1, 2020.

²⁶ FDA. *WARNING LETTER: CBD Gaze MARCS-CMS 607299*. May 26, 2020. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cbd-gaze-607299-05262020>. Accessed March 4, 2021.

²⁷ FDA. *FDA News Release: FDA Warns Companies Illegally Selling CBD Products to Treat Medical Conditions, Opioid Addiction*. April 23, 2020. <https://www.fda.gov/news-events/press-announcements/fda-warns-companies-illegally-selling-cbd-products-treat-medical-conditions-opioid-addiction>. Accessed November 30, 2020.

²⁸ FDA. *FDA News Release: FDA, FTC warn company marketing unapproved cannabidiol products with unsubstantiated claims to treat teething and ear pain in infants, autism, ADHD, Parkinson’s and Alzheimer’s disease*. October 22, 2019. <https://www.fda.gov/news-events/press-announcements/fda-ftc-warn-company-marketing-unapproved-cannabidiol-products-unsubstantiated-claims-treat-teething>. Accessed November 30, 2020.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² FDA. *WARNING LETTER: KOI CBD LLC MARCS-CMS 593391*. November 22, 2019. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/koi-cbd-llc-593391-11222019>. Accessed December 7, 2020.

³³ *Id.*

³⁴ *Id.*

³⁵ E.g. Pulse. *Pulse CBD Kids 15000mg – Strawberry*. <https://pulsehempco.com/products/pulse-cbd-kids-15000mg-strawberry>. Accessed August 16, 2023; *Miami Herald. Best CBD Gummies for Kids: Safest Brands, Dosage, and Buyer’s Guide*. <https://www.miamiherald.com/health->

ailments associated with pregnancy. However, limited research has been conducted on the long-term effects of CBD on health in vulnerable populations.

CBD edibles share many attributes and risks with food and dietary supplements, so the new regulatory framework should ensure that existing policies that provide for safety and accurate labeling of food and dietary supplements be applied to CBD products, either by regulating these products as a subcategory of foods, or by creating a separate regulatory framework that incorporates similar basic requirements. This includes ingredients labeling, prohibitions on drug claims, and current good manufacturing practices/preventive controls requirements.

However, it is also clear that FDA will not be able to adequately address the issues observed with CBD using only its authority over food and dietary supplements, as the agency has to date faced substantial problems preventing misbranded and adulterated dietary supplements from being marketed to consumers due to the growing market. The limited authorities given to FDA by the Dietary Supplement Health and Education Act of 1994 (DSHEA) makes the almost \$60 billion dietary supplement marketplace a “Wild West.”³⁶ Simply forcing FDA to regulate a \$5 billion CBD industry as supplements without clear authority and resources will overwhelm an already overburdened agency.

Clearly, new authority and resources are needed to ensure the safety of CBD products, as well as food and dietary supplements more generally. Essential elements include the following:

- A. Using existing food and dietary supplement authorities as a foundation for a CBD framework.
- B. Clearly defining regulatory pathways and authorities for CBD products.
- C. Ensuring new CBD uses undergo robust premarket approval.
- D. Establishing a mandatory registration of factories producing CBD products and product listing, requiring companies to notify FDA when introducing new products.
- E. Giving FDA express authorities for CBD labeling and marketing, including the authority to prevent products from being marketed to children and other vulnerable groups by requiring age restrictions for purchasing, mandating standardized warnings, and child-proof packaging, as well as require clear labeling identifying CBD products and dosages.
- F. Requiring companies to submit to FDA evidence substantiating their claims.
- G. Enhancing FDA’s post-marketing authorities to address misbranding and adulteration by ensuring that mandatory recall authority applies to all CBD products, requiring that all adverse events are reported to FDA, and authorizing civil penalties.

[wellness/article264168011.html](https://www.wellness.com/article264168011.html). Accessed August 16, 2023 (Note: Although the linked product listings are not expressly marketed to children, the article has a disclaimer that “We may earn a commission if you make a purchase through one of our links. The newsroom and editorial staff were not involved in the creation of this content.”).

³⁶ Nutritional Outlook. *Dietary supplement sales success post-COVID: How can industry keep the momentum going after the pandemic?*. May 26, 2021. <https://www.nutritionaloutlook.com/view/dietary-supplement-sales-success-post-covid-how-can-industry-keep-the-momentum-going-after-the-pandemic>. Accessed August 9, 2023; National Public Radio. *On Amazon, Dubious 'Antiviral' Supplements Proliferate Amid Pandemic*. July 27, 2020. <https://www.npr.org/2020/07/27/894825441/on-amazon-dubious-antiviral-supplements-proliferate-amid-pandemic>. Accessed August 9, 2023.

- H. Ensuring adequate quality control measures are in place by allowing FDA to set contamination limits for toxic elements or other hemp-derived chemicals—such as THC—by administrative order, requiring manufacturers to conduct final product testing, and requiring them to report positive test results to the agency.
- I. Substantially increasing the budget available for enforcement, well beyond the Office of Dietary Supplement Programs’ (ODSP) current \$11 million budget, which is insufficient to monitor a \$60 billion industry and carry out appropriate enforcement actions.

We provide further details on these recommendations in the section below.

IV. Recommended Elements for a CBD Framework

A. Existing Authorities for Food and Dietary Supplements Should Serve as a Foundation for CBD Products

Regardless of whether CBD products are considered to be a subset of foods or are provided a separate and distinct regulatory framework from foods, the misbranding and marketing provisions that currently apply to foods and supplements should serve as a basis for regulating these products. For example, edible CBD products should be required to bear a nutrition or supplement facts panel and ensure permissible claims are substantiated. As with foods and dietary supplements, disease claims should be prohibited on CBD products that are not approved drugs.

In addition, the current good manufacturing practices (cGMPs), preventive controls, and other post-market authorities that currently apply to foods and supplements should also apply to CBD products. CBD manufacturers should be required to report recalls and other “near miss” events to the reportable foods registry.

While being able to provide a basis for a CBD framework, FDA’s current food and supplement oversight is inadequate to safely regulate the food, supplement, or CBD market. A CBD framework should compensate for the existing gaps in FDA’s oversight and the specific safety concerns of CBD as described in this section.

B. Clearly Defined Regulatory Pathways and Authorities for CBD Products

It should be clear which regulatory pathways, enforcement mechanisms, and authorities CBD is subject to when it is added to foods or dietary supplements. Foods and dietary supplements currently have different regulatory pathways. Premarket approval, permissible marketing claims, and the offices charged with oversight differ depending on whether a product is legally a conventional food or dietary supplement. Depending on how CBD is used, a CBD product could look like a food (e.g., a CBD brownie with a qualified health claim), a supplement (e.g., a CBD pill with structure and function claims), or fall confusingly in between. If CBD is allowed in foods and dietary supplements, agencies and industry should be given clear guidance on who has authority to regulate the different types of CBD products and how the products are to be regulated.

C. Robust Premarket Approval

FDA has stated that CBD is not generally recognized as safe (GRAS), a designation that could otherwise allow manufacturers to evade seeking FDA review of the chemical as a food additive or dietary ingredient. If CBD is allowed in foods and dietary supplements, Congress should ensure that “new uses” of CBD (e.g., marketing CBD with new dosages, forms, formulas, or in combination with other food or dietary ingredients) will require premarket approval. “New uses” would include uses that are currently on the market, but have not been subject to premarket approvals.

Because CBD is a pharmacologically active chemical, it can have varying effects at different doses and is subject to adverse interactions with other ingredients. Therefore, it is imperative that new CBD uses be reviewed and vetted by a government agency before entering the market. Requiring companies to submit new uses for premarket review will also help agencies know how CBD is consumed and identify potential safety issues. Congress should accomplish this goal by closing the GRAS loophole not only for CBD, but more generally for all new food chemicals, a measure endorsed in the Ensuring Safe and Toxic Free Food Act of 2022.³⁷

D. Mandatory Facility Registration and Product Listing

CBD manufacturing facilities should be required to register with the FDA, just as food and dietary supplement facilities are already required to register with the FDA. However, food and supplement companies are not currently required to list their products with the FDA.

Members of Congress have been engaged in bipartisan efforts to extend a mandatory product listing requirement to dietary supplements.³⁸ Congress should adopt this policy and ensure that these listing requirements extend to products that contain CBD. Prior to marketing their products, companies should be required to list those products in a publicly available government database. This listing should require relevant safety and product information such as the company name and address, safety information related to each ingredient, serving sizes, claims, warnings, instructions for use, and enforcement actions against the product. Each product label should be given an identification number or barcode to help consumers find the product in the government database. Such a database will help agencies and consumers know what is on the market and identify problem CBD products and dietary supplements more generally.

E. Labeling and Marketing

While FDA does have limited existing authority to require warnings and restrictions on conditions of use for food additives, the agency should be given more express authority to prevent CBD products from being marketed to children and other vulnerable groups by imposing

³⁷ S.4316 - Ensuring Safe and Toxic-Free Foods Act of 2022 117th Congress (2021-2022).

³⁸ S.4090 - *Dietary Supplement Listing Act of 2022*. <https://www.congress.gov/bill/117th-congress/senate-bill/4090>, Accessed August 13, 2023; S.4348 - *Food and Drug Administration Safety and Landmark Advancements Act of 2022*. <https://www.congress.gov/bill/117th-congress/senate-bill/4348/text#toc-1dc3b75fde45fb40299068caab50cab152>. Accessed August 13, 2023.

age restrictions and labeling requirements on such products. FDA should also have authority to require CBD-specific disclaimers that warn of the dangers of CBD and the lack of FDA review of product claims.

i. Age Restrictions

As the long-term effects of CBD use among children are not well understood, the Epidiolex trials found that high-dose CBD may interact with other drugs or cause liver injury, diarrhea, drowsiness, or mood changes. FDA notes that children are “a vulnerable population that may be at greater risk for adverse reactions due to differences in the ability to absorb, metabolize, distribute or excrete a substance such as CBD.”³⁹ Given these concerns, a new framework should limit access and marketing of CBD products to children. Specifically, the framework should set age limits for purchasing CBD products similar to the restrictions now in place for tobacco products, prohibit marketing CBD products to children (e.g., prohibit packaging, products, or advertisements that appeal to children), and require childproof packaging.

ii. Labeling requirements

To prevent inadvertent consumption of CBD, products containing CBD should be labeled in a standardized way, such as with an icon with standardized text, for consumers to easily identify products as containing CBD.

The labels should also be required to accurately and clearly display the dosage of CBD and bear specific warnings (e.g., “Should not be consumed by pregnant individuals”), with discretion to design formatting and placement to enhance noticeability (e.g., color, rotating warnings). FDA should be allowed to adjust the content of the warnings as additional health risks become known.

F. Claims

Companies should be required to submit evidence substantiating any structure and function claims prior to marketing those claims. Additional restrictions may also be needed to prevent CBD products from being marketed with misleading health claims, nutrient content claims, and structure and function claims.

G. Enhanced Post-Market Authorities

A new framework for CBD should close gaps in the agency’s post-market authorities over foods and dietary supplements. This includes:

- Ensuring that mandatory recall authority applies to all CBD products, even if they are adulterated with other pharmaceutical ingredients or misbranded with drug claims, which would exclude them from the definition of “food” under existing law and therefore put them beyond the reach of FDA’s current mandatory food recall authority.
- Requiring manufacturers to report all adverse events to FDA.

³⁹ FDA. HIGHLIGHTS OF PRESCRIBING INFORMATION.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/2103651b1.pdf.

- Civil and criminal penalties for violations of cannabis regulations should be allowed, so that the agency is not required to work with the Department of Justice to pursue criminal violations, a labor-intensive process that cannot be utilized for large numbers of infractions.
- Appropriate adulteration standards that address the risks associated with cannabis products should be used for CBD products.

H. Enhanced quality control measures

A new framework should ensure that CBD products are safe and adhere to strict quality control measures by:

- Allowing FDA to set contamination limits for toxic elements by administrative order. We urge Congress to authorize FDA to extend this authority to all foods, as similar issues with contamination have occurred for non-CBD products and have particularly hindered FDA's efforts to limit heavy metals contamination in foods marketed for infants and young children.⁴⁰
- Requiring manufacturers to conduct final product testing for pathogens, contaminants, and CBD/THC content, with test results exceeding the regulatory standards reported to the agency. FDA should be given authority to apply this same requirement to other food or dietary supplement categories that are high-risk, including infant formula.

I. Adequate funding for CBD monitoring, regulation and enforcement

When enacted in 1994, the supplement marketplace was a \$4 billion industry, comprised of about 4,000 unique products.⁴¹ Online retail and social media were largely non-existent. Since DSHEA's passage, supplement sales have grown to almost \$60 billion⁴² with an estimated 95,000 products.⁴³ Bad actors have increasingly turned to online platforms and social media influencers to promote products with illegal claims and adulterants, making it difficult for FDA to monitor the marketplace for illegal products and take requisite enforcement action. DSHEA has not provided FDA with the tools to adapt to this growing industry and increased online presence. In addition, the testing of food and supplement facilities for pathogens and contaminants is woefully insufficient.

As FDA's current food and supplement oversight is significantly overburdened, new mandates to regulate CBD would be meaningless unless FDA is provided with sufficient funding to monitor, regulate, and carry out effective enforcement action. Therefore, Congress should provide FDA

⁴⁰ See FDA. Summary of FY 2024 Legislative Proposals. <https://www.fda.gov/media/166049/download>. Accessed August 16, 2023.

⁴¹ FDA. *Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight*. February 11, 2019. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary>. Accessed August 16, 2023.

⁴² Nutritional Outlook. *Dietary supplement sales success post-COVID: How can industry keep the momentum going after the pandemic?*. May 26, 2021. <https://www.nutritionaloutlook.com/view/dietary-supplement-sales-success-post-covid-how-can-industry-keep-the-momentum-going-after-the-pandemic>. Accessed August 9, 2023.

⁴³ FDA. Summary of FY 2024 Legislative Proposals. <https://www.fda.gov/media/166049/download>. Accessed August 16, 2023.

with adequate funding to carry out premarket approval review of new CBD products; testing of monitoring of CBD products to detect pathogens, contaminants, and accurate dosage; and regularly scheduled inspections for cGMP violations.

V. Conclusion

Currently, FDA's inadequate funding and authorities cannot safely regulate foods and supplements. Therefore, a CBD framework needs to provide additional authorities and funding needed to safely regulate CBD as described in this letter.

Although this comment mainly focused on CBD, Congress should consider how a new framework should regulate other new hemp-derived chemicals that may be marketed in foods and dietary supplements. There are hundreds of other hemp-derived ingredients, including delta-9-tetrahydrocannabinol (THC)—a psycho-active cannabinoid—and more than 100 compounds chemically related to THC.⁴⁴ Many of these substances are not well studied—or studied at all—for safety or effectiveness.

Finally, when creating a new framework for CBD products, Congress should take this opportunity to address the public health risks in our current food and dietary supplement marketplace more generally. The existing regulatory gaps discussed in this comment are not specific to CBD, and the majority of our recommended CBD reforms would reduce the fraud and public health issues that persist in our foods and dietary supplements.

It would be a wasted opportunity to develop a framework that would make CBD-containing foods and dietary supplements safer, while not addressing the dangers in foods and supplements more generally, with CBD being simply a particularly noteworthy exemplar. *All* our foods and dietary supplements, not just products with CBD, need to be safe.

We thank you for the opportunity to provide these comments and urge Congress to act swiftly to protect consumers from fraudulent and unsafe CBD products. If you have any questions or would like to discuss our recommendations in more detail, please contact Jensen N. Jose, CSPI's Regulatory Counsel, at jjose@cspinet.org.

Respectfully submitted:

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⁴⁴ National Institutes of Health (NIH). *Marijuana Research Report: What is marijuana?*. July 2020. <https://www.drugabuse.gov/publications/research-reports/marijuana/what-marijuana>. Accessed November 24, 2020.