Council for Responsible Nutrition
1828 L Street, NW, Suite 810 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org
The Science Behind the Supplements

August 17, 2023

Dear Honorable Chairs and Ranking Members:

Thank you for the opportunity to provide information on the best way to provide a legal pathway for non-intoxicating hemp-derived cannabinoid (CBD) products in the marketplace. The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, DC, is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 200 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety and also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics.

In this submission, CRN addresses many of the questions raised by the Committees' Request for Information issued on July 27, 2023 and would be happy to provide additional information at the Committees' request.

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?

Questions 1, 2, and 3 ask about the current status of the CDB market. The Agriculture Improvement Act of 2018 (2018 Farm Bill) removed hemp and its non-THC constituents from controlled substances scheduling, thus opening a new market for CBD products. While this new market initially flourished following the enactment of the 2018 Farm Bill, FDA inaction has since created uncertainties that have damaged the industry. FDA's continued inaction creates safety risks for consumers by creating a market which many current, knowledgeable supplement companies are hesitant to enter, and in which FDA oversight is limited.

Congress initially anticipated that, with the removal of hemp and its non-THC constituents from scheduling, FDA would immediately provide pathways for the marketing of hemp-based products under

its existing legal jurisdiction. FDA has ample authority to regulate these products as food, dietary supplements, cosmetics and over-the-counter and prescription drugs with the prescribed authorities in the current federal Food, Drug, and Cosmetic Act (FDCA) and related regulations. Even though Congress and industry have requested that FDA use this authority there has been no substantive action. As a result, the CBD industry has since languished.

We believe that if FDA had worked expeditiously on a regulatory pathway to legally market CBD when the 2018 Farm Bill was enacted, the questions raised in this RFI would have already been addressed. Instead, FDA has spent the past five years metaphorically wringing its hands about this authority, ignoring Congress' directive, watching from the sidelines as a sizable, but unpredictable CBD marketplace evolved without meaningful enforcement of legal requirements, and ignoring (*even denying the existence of*) credible, well-conducted research that was presented to the agency to demonstrate the safety of well-made CBD products.

Pathway

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

FDA has raised three separate areas of objection to regulating CBD through the existing pathway for dietary supplements as established by the Dietary Supplement Health and Education Act of 1994 (DSHEA):

1) the Drug Preclusion issue for an ingredient previously marketed as a drug;
2) the available tools and regulatory authority for appropriate oversight of the products; and
3) questions about the safety of CBD.

Each of these points will be addressed separately below. Safety will be addressed in response to Questions 11-19.

The Drug Preclusion Conundrum — And Three Different Solutions

Shortly after the passage of the 2018 Farm Bill, FDA objected to the inclusion of hemp-derived CBD in dietary supplements, citing the "drug preclusion" provision that was added to the FDCA by DSHEA. This section prohibits the introduction of a dietary supplement containing the same "article" that has previously been approved as a drug or studied in substantial clinical investigations which have been made public as a drug.

Specifically, the drug preclusion section of DSHEA (21 U.S.C. 321 (ff)(3)(B)) provides that a dietary supplement does –

> *(B) not include —*

> *(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or*
>
> *(ii) an article authorized for investigation as a new drug, antibiotic, or biologic for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this [Act] . . .* [1]

This provision essentially establishes a "race to market" between dietary supplements and pharmaceuticals that use the same ingredients. If the supplement is marketed first, the two categories (supplements and drugs) essentially "share" the ingredient; but if the drug is marketed first, or even if the article is first studied in substantive clinical trials that are made public, the drug industry can claim a monopoly over the article and prevent its eventual marketing in dietary supplements.[2]

That is essentially what happened to CBD when, in 2019, FDA announced that CBD was precluded from use in dietary supplements due to it being approved in 2018 in the drug Epidiolex, a prescription medication containing high dosages of purified CBD for indications related to seizures.

Even if FDA is correct in its assessment that Epidiolex predated any legal supplements containing CBD, the agency has several options under the existing framework that would have allowed the inclusion of CBD in dietary supplements.

1. First, FDA could determine that the pharmaceutical and dietary supplements are not using the same "article" and thus, these low dosage products are not precluded by the drug preclusion provision. CBD-containing dietary supplements that have been brought to FDA for review (*and objected to by the agency*) in a series of New Dietary Ingredient Notifications over the past five years, typically contain 20-65 mg of CBD per serving, whereas a standard dose of Epidiolex delivers 1,000 mg or more of purified CBD. In addition, CBD in these supplements was provided as part of a "full spectrum hemp extract" that contained a variety of other cannabinoids and plant constituents not found in Epidiolex. Further, Epidiolex is indicated for the control of seizures whereas low dosage CBD products (whether isolated CBD or full spectrum hemp containing CBD) are labeled for help with sleep, relaxation, mild anxiety and occasional pain relief. FDA could determine based on any of these differences that the two types of products are sufficiently different in dosage and composition that they are not the same article.

2. Alternatively, FDA could invoke the rulemaking authority expressly granted to it by the statute and initiate a notice and comment rulemaking that would allow the legal marketing of CBD as a supplement. Even if the agency determined that CBD used in Epidiolex and in supplements are the same "article," Section 321 (ff)(3)(b) clearly grants the FDA discretion to issue a regulation as

[1] 21 U.S.C. § 321 (ff)(3)

[2] Various aspects of FDA's interpretations of the drug preclusion provision as it applies to a range of ingredients are currently the subject of a Citizen Petition before FDA filed by CRN earlier this year. See CRN Citizen Petition, submitted May 9, 2023, https://www.crnusa.org/sites/default/files/pdfs/comments-pdfs/CRN-CitizenPetition-FDA-DrugPreclusion050923.pdf.

an exception to the general drug preclusion rule that the article "would be lawful" under the Act.[3] CRN has suggested to FDA that there is ample justification for this exception given the prior controlled substance status of hemp-derived CBD.[4] The typical "race to market" envisioned by the drug preclusion principle could not properly function since the article was a Schedule I substance and was prohibited from being sold as a dietary supplement prior to the passage of the 2018 Farm Bill.

3. A third option available to FDA to bypass the drug preclusion issue is to ask Congress to amend the law to grant a special case for CBD. H.R. 1629, the Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2023, in the current Congress would do just that.[5] It provides that "notwithstanding section 201(ff)(3)(B) of the Federal FDCA (21 U.S.C. 321(ff)(3)(B)), hemp, cannabidiol derived from hemp, and any other ingredient derived from hemp shall be lawful for use under the Federal FDCA (21 U.S.C. 301 et seq.) as a dietary ingredient in a dietary supplement…." It would be a far less disruptive solution and require less time to fully implement, but FDA has opposed this option as well.

So, when FDA suggests that its hands are tied by the drug preclusion language in the FDCA, Congress should inquire why none of these options have been pursued.

Available Tools and Authorities for Dietary Supplements

FDA's second reason for seeking a new regulated category for CBD is that a "new framework could enable harm reduction safeguards to help people understand and minimize their risks from using CBD."[6] This statement, and the ensuing new tools and authorities it is seeking, either ignore or dismiss the wide range of risk reduction tools available to FDA for dietary supplements.

DSHEA defines a "dietary supplement" to include "an herb or other botanical" and a "concentrate, metabolite, constituent, extract or combination."[7] There is no question that CBD falls squarely within this definition. However, the agency now states that "FDA has concluded that a new regulatory pathway for CBD is needed that balances individuals' desire for access to CBD products with the regulatory oversight needed to manage risks." It raises the question why the existing dietary supplement framework would not suffice.

The regulatory framework for dietary supplements provides ample tools by which FDA can manage the risk associated with these products. Even as FDA calls for new authority, asserting that the current framework is "not appropriate to regulate CBD products," one wonders how the current tools are not sufficient. DSHEA gives FDA authority in these areas:

- ✓ **Good Manufacturing Practices** – Good Manufacturing Practices (GMPs) regulations specific to dietary supplements allows FDA to prevent the introduction of contaminants like heavy metals, pathogens or solvents in the finished products.[8] These GMP requirements, which have been

[3] See 21 U.S.C. § 321 (ff)(3)(B).
[4] See CRN Citizen Petition to FDA regarding CBD submitted June 16, 2020, https://www.regulations.gov/document/FDA-2020-P-1582-0001.
[5] Cite to H.R. 1629, https://www.congress.gov/bill/118th-congress/house-bill/1629/history?s=1&r=6.
[6] FDA Technical Assistance on Considerations for a Regulatory Framework for Cannabidiol (CBD) and other Cannabinoid Hemp Products (2023).
[7] 21 U.S.C. § 321(ff).
[8] 21 CFR Part 111.

fully incumbent on dietary supplements since 2010, prescribe that all incoming batches of raw materials be tested for their potency, purity, strength and composition; they require manufacturers to set specifications for their products and to demonstrate compliance with those specifications, mandate finished product testing and generally prescribe a range of sanitation requirements for these facilities. (See further discussion in Answer to Question 20.)

- ✓ **Mandatory Recall Authority** – FDA seeks mandatory recall authority over this new category. FDA already has such authority over dietary supplements.[9] As dietary supplements are regulated as food, they are subject to the mandatory recall authority provided to FDA for food, which would be available to FDA if it discovered potential health risks from CBD-containing dietary supplements.[10] It is interesting to note that the first use of this new mandatory recall authority for food by the agency occurred with respect to a dietary supplement.

- ✓ **Safety Standard for the Removal of Products** – A safety standard for the removal of an unsafe ingredient already exists for dietary supplements. A dietary supplement is considered "adulterated" if it—

  (1) If it is a dietary supplement or contains a dietary ingredient that—
  (A) presents a significant or unreasonable risk of illness or injury under—
  (i) conditions of use recommended or suggested in labeling, or
  (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;
  (B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;
  (C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or
  (D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.[11]

- ✓ **Pre-market Review of Safety of New Products** – The NDI provision of DSHEA establishes a process for notification of FDA for bringing new ingredients, like CBD, to market. Nearly 30 years after the law's passage, FDA is still working on the specifics of these requirements, but the statute is clear that "a dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 342(f) of this title" unless it meets one of the pathways that demonstrate the product is "reasonably expected to be safe."[12]

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[9] 21 U.S.C. § 350l. This provision was added by section 206 of the FDA Food Safety Modernization Act of 2011 (FSMA).
[10] See also Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff, https://www.fda.gov/media/117429/download
[11] 21 U.S.C. § 342(f)(1).
[12] 21 U.S.C. § 350b.

- ✓ **Mandatory Adverse Event Reporting** – All dietary supplements are subject to mandatory reporting of any serious adverse events[13] (all adverse event reports, whether serious or not, must be reviewed and maintained by the manufacturer for 6 years). A "serious adverse event" is one that results in death; a life-threatening experience; inpatient hospitalization; a persistent or significant disability or incapacity; or a congenital anomaly or birth defect; or requires, based on reasonable medical judgment, a medical or surgical intervention to prevent one of these outcomes.[14] If the responsible party becomes aware of a non-serious adverse event associated with the product, it is still required to retain that report for six years and make it available to the FDA upon request.[15]

- ✓ **Facility Registration** – FDA indicates it wants to maintain a registry of all facilities that produce CBD. It already has such authority for dietary supplements. Pursuant to the food facility registration requirements of the FDA Food Safety Modernization Act (FSMA), dietary supplement facilities must register with FDA every two years.[16]

- ✓ **Oversight of Product Labeling** – FDA currently has extensive oversight of dietary supplement labeling that could be utilized for labeling of dietary supplements containing CBD as well.[17] DSHEA authorized FDA to prescribe requirements for dietary supplement labeling and that mandate is described extensively in regulation.[18] Among these requirements: a mandatory Supplement Facts box, complete listing in descending order of their predominance, the quantity of each ingredient, requirements that label claims must be truthful and supported by evidence, and a prohibition on claims to diagnose, cure, mitigate, prevent, or treat a disease.

- ✓ **Upper Limits on Ingredient Contents** – DSHEA provides that dietary supplements may not present "a significant or unreasonable risk of illness or injury under…conditions of use recommended or suggested in labeling"[19] and FDA has precedent of imposing maximum serving levels on specific ingredients. (See further discussion in Answer to Question 16.)

In sum, DSHEA provides a range of tools for FDA to mitigate risks and protect consumers while allowing access to safe botanicals, like CBD. Other possible safeguards that FDA imagines for a new category of cannabis products could be achieved under the existing framework. While FDA currently lacks the authority to require that dietary supplements be listed with the agency (a concept referred to as "dietary supplement listing"), legislation to impose dietary supplement listing on all supplements could be enacted and implemented far more quickly than the creation of an entirely new category of regulated products. (CRN has supported legislation to establish dietary supplement listing for all dietary supplements.) If FDA effectively limited THC levels in the products and required cautionary label statements about the risk of ingestion by children, additional age purchase restrictions would be unnecessary.

These are the risk mitigation tools that FDA has called for in a new regulatory category for CBD-containing products. All these safeguards and tools for effectively minimizing risk either already exist or

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[13] 21 U.S.C. § 379aa-1.
[14] 21 U.S.C. § 379aa-1(a)(2).
[15] 21 U.S.C. § 379aa-1(e)(1).
[16] 21 U.S.C. § 350d.
[17] 21 USC § 343(s).
[18] 21 CFR 101.
[19] 21 U.S.C. § 342(f), https://www.law.cornell.edu/uscode/text/21/342.

could be developed and implemented far more efficiently within the existing regulatory framework for dietary supplements. Instead, FDA downplays, underestimates and misrepresents its ability to enforce the law and to protect consumers as justification for creating a new Center within FDA and a new regulatory category that undermines the existing structure of the FDCA.

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?

Question 5 and its subparts ask how Congress and/or FDA should define various products, as well as what substances/ingredients should be limited or excluded from a regulatory framework. Under the current DSHEA dietary supplement framework, CRN does not believe that Congress and/or FDA has to create specific definitions, limitations, or other exclusions for us of hemp-derived ingredients in dietary supplements. The existing framework under DSHEA already adequately allows FDA to make decisions about what is and is not included in a dietary supplement.

DSHEA defines both the type of ingredients that are permitted in dietary supplements and sets out safety standards that limit or exclude the use of these ingredients. Thus, an ingredient first must be one of the permitted ingredients and then can be used only if it meets the safety standards that were created by DSHEA. We provide more detail below.

With regard to creating a definition for CBD or cannabinoid-containing hemp-products, this is unnecessary for dietary supplements. An ingredient derived from the hemp plant can be used in dietary supplements if it fits into one of the dietary ingredient categories listed under 21 U.S.C. § 321(ff)(1). This list includes "an herb or other botanical" (21 U.S.C. § 321(f)(1)(C)). As hemp is a botanical, substances derived from hemp are clearly permitted in dietary supplements, provided the ingredient then meets the appropriate safety standards under DSHEA.

Dietary ingredients must not "present a significant or unreasonable risk of illness or injury under" either (1) the conditions of use recommended in the labeling (e.g., conditions set out in directions, warnings, and other label statements); or (2) if no conditions are recommended, the ingredient must meet the safety standard under ordinary conditions of use (*see* 21 U.S.C. § 342(f)). Together both the list of permitted ingredients and the safety standards place appropriate safeguards around hemp-derived

ingredients when used in supplements, negating any need to further define hemp products or specifically limit or exclude the cannabinoids or other substances derived from this botanical.

CRN is concerned that Congress is considering the use of a regulatory framework in a manner that is not consistent with the overarching framework of the FDCA and structure of FDA. The FDCA and FDA do not regulate products on an ingredient or ingredient source level. There are several ingredients that when manufactured, extracted, or otherwise processed in different manners create products that are regulated under separate legal frameworks. For example:

- ✓ Caffeine is available from a wide variety of sources and is used in products that span numerous regulatory frameworks, including conventional food (coffee, soda, etc.), dietary supplements, drugs, and cosmetics.
- ✓ Crops like potatoes and corn are common sources of ingredients used in food, but these vegetables can also be used to create distilled spirits like vodka and bourbon.

These ingredients in the examples above are regulated based on the characteristics and intended use of the end product, rather than at the ingredient level. If FDA started regulating ingredients that have uses across a spectrum of products at the ingredient level, the agency would be twisted into an unworkable regime of mini-ingredient offices, each having responsibility for administering and enforcing the laws and regulations across multiple product categories.

We also want to address Congress' question about whether FDA should regulate "semisynthetic" and "biosynthetic" substances, which are still not scheduled under the Controlled Substances Act (CSA). We reiterate that the dietary supplement framework, both the list of permitted ingredients and the safety standards, continues to be applicable and appropriate to guide how FDA would handle these ingredients for dietary supplements. FDA has taken the position in draft guidance that synthetic botanicals are not permitted in dietary supplements; however, the agency has left the door open to whether the use of synthetic copies of botanicals are permissible (*see* New Dietary Ingredients (NDI) and Innovation in Dietary Supplements: A Call for New Compliance and Enforcement Strategies). CRN supports the position that synthetic copies should be permitted as it provides companies and consumers with a number of potential benefits, such as allowing companies to engage in more sustainable ingredient production tactics and reducing the cost of products for companies and consumers.

Such a position would mean that constituents not found in hemp plants at significant levels and that must be further manipulated to create concentrated amounts, like Delta-8 THC, would likely not be considered a botanical under 21 U.S.C. § 321(ff)(1)(C). Even if considered to be an appropriate dietary ingredient, however, supplement safety standards would limit or exclude use if a substance presents an unreasonable risk of illness or injury. FDA has the opportunity to clarify synthetic botanical use through its long overdue new dietary ingredient guidance.

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?

The existence of other dietary ingredients that present potential risks to consumers and FDA's response to those ingredients amply demonstrates that FDA has the ability to impose risk reduction strategies under the existing framework for dietary supplements. In the case of kratom, FDA has stated clearly that, while it is indeed a dietary ingredient, it is a new dietary ingredient for which the safety has not been demonstrated. FDA has denied several NDI notifications for kratom, launched multiple seizures under DSHEA allowing it to pursue kratom products even more aggressively, but to date, FDA has been reluctant to use that authority. Similarly, with pure powdered caffeine, FDA has formally announced that these high concentrations of caffeine present a significant or unreasonable risk to consumers and has banned their sale. It has authority under DSHEA to issue import alerts, conduct seizures, impose voluntary or mandatory recalls, and issue injunctions or civil fines for the sale of such products. These authorities would be available to FDA for CBD-containing dietary supplements if they were marketed outside the permitted requirements of a recognized NDI notification.

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?

With FDA's refusal to regulate CBD under its existing authority and the resulting lack of regulatory clarity, consumers are exposed to an unpredictable and wide range of products – some well-made and accurately labeled, and others that are mislabeled, contain too much, too little, or even no CBD, ones containing contaminants, or intoxicants like THC, Delta-8 THC, or others, or that impermissibly claim to treat a range of diseases. Consumers deserve to have a CBD marketplace that is regulated and predictable. Allowing CBD to be marketed in dietary supplements under the current framework would address these needs.

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?

Five years ago, Congress enacted the 2018 Farm Bill that included provisions expressly removing hemp and its constituents from the Controlled Substance Schedules. Prior to that legislation, the CSA did not distinguish between marijuana (that contains various levels of the compound delta-9-tetrahydrocannabinol (THC), the major psychoactive component of marijuana), and hemp, which contains other cannabinoids, but not appreciable amounts of THC. Congress explicitly delineated that difference by requiring that hemp shall not contain more than 0.3 percent THC.

In addition, the legislation expressly directed that,

> *"Nothing in this subtitle shall affect or modify … the Federal Food, Drug, and Cosmetic Act; … Section 351 of the Public Health Service Act; or … the authority of the Commissioner of Food and Drugs and the Secretary of Health and Human Services … to promulgate Federal regulations and guidelines that relate to the production of hemp under the Act."*[20]

In other words, Congress fully anticipated that, with the removal of hemp and its non-THC constituents from scheduling, FDA would expeditiously provide pathways for the marketing of hemp-based products under its existing legal jurisdiction. FDA has ample authority to regulate these products as food, dietary supplements, cosmetics and over-the-counter and prescription drugs with the prescribed authorities in the current federal FDCA and related regulations.

FDA should use existing legal authority and existing regulated categories to regulate CBD where it fits into those categories. FDA has traditionally regulated products according to their intended usage and in certain cases, their routes of administration (Dietary supplements must be ingested; topical or inhaled products cannot be dietary supplements.) There is no reason that hemp/cannabis products should be treated differently. Where a current regulatory pathway exists, it should be used.

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?

FDA's failure to establish a regulatory pathway for CBD has forced states to enact their own disparate policies to protect consumers. This has resulted in a patchwork of laws, which is detrimental to the industry.

Most states allow the sale of CBD (with a THC level of less than 0.3%), however, there are restrictions in place that differ state by state, creating a complicated marketplace. For example, CBD remains technically illegal in Idaho, unless there is 0% THC and the product is classified as "not marijuana" under the state code.[21] Similarly, other states have either implemented or are considering THC limits, including Alaska, Louisiana, and Oregon. There is also a lack of consistency in labeling requirements; Florida requires extensive information such as the number of milligrams of each marketed cannabinoid per serving, a website address, and expiration date, whereas some states, like Connecticut, currently do not have labeling requirements whatsoever. Additionally, many states have certain restrictions over the use of CBD in foods and dietary supplements, while others have implemented age restrictions. This patchwork of laws is unsustainable and federal intervention is necessary to create uniformity for industry

[20] 7 U.S.C. § 1639r - Regulations and guidelines; effect on other law.
[21] See Idaho Code§ 37-2701(t)

and consumers alike. Many states have actually modeled their policies after DSHEA, which is the standard FDA should adopt.

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?

In the absence of federal agency action, many states have rolled up their sleeves and developed their own regulations for non-intoxicating hemp-derived cannabinoid products in the marketplace. CRN recognizes that patchwork state regulations can be difficult for manufacturers and consumers alike and supports a national standard that recognizes the difference between non-intoxicating hemp-derived cannabinoid products and other cannabis-related products. Perhaps once a federal standard is developed, states will be able to use that system as a benchmark to further refine their own regulations.

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.

A large body of evidence is available on the safety of CBD and CBD-containing hemp extracts. In fact, other government bodies have established recommended maximum upper intake levels of CBD based on the available safety data. In 2020, the UK Food Standards Agency recommended an upper limit of 70 mg per day CBD for healthy adults, based on a review of evidence by the UK Committee on Toxicity.[22] Later that year, the Australian Therapeutic Goods Administration also released their safety assessment with the overall conclusion that "cannabidiol presents a good safety and tolerability profile at the low dose range of under 60 mg/day."[23] In 2022, Health Canada's Science Advisory Committee on Health Products Containing Cannabis issued a review of CBD, stating that "CBD is safe and tolerable for short-term use (a maximum of 30 days) at doses from 20 milligrams per day (mg/day) to a maximum dose of 200 mg/day via oral administration for healthy adults provided they discuss the use of all other medications and substances used with their pharmacist."[24]

FDA has been presented with a vast amount of safety information over the past five years from various stakeholders, including CRN. In 2019, CRN responded to FDA's Hearing and Request for Comment on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds. In that heavily referenced submission, citing global data assessing the safety of CBD, CRN wrote:

> "The safety of orally ingested CBD has been comprehensively reviewed in a series of reports from recognized authoritative scientific bodies (RASB) and published

[22] https://www.food.gov.uk/news-alerts/news/food-standards-agency-sets-deadline-for-the-cbd-industry-and-provides-safety-advice-to-consumers
[23] https://www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf
[24] https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/health-products-containing-cannabis/review-cannabidiol-health-products-containing-cannabis.html#a3.3

> systematic reviews. While some reviews have focused on potential toxicity from CBD exposure, others have examined CBD safety in the context of adverse events (AEs) and its addictive potential. Generally, CBD, when orally ingested appears to have a wide margin of safety. It may interact with certain medications via inhibition of certain liver cytochrome P450 enzymes, but these risks likely could be managed by cautionary consumer communications."[25]

In the following year, CRN provided the agency with a safety assessment conducted by a group of independent third-party scientific experts who proposed a tolerable upper intake level for CBD in dietary supplements of 40 mg/day.[26] This assessment, along with the safe levels/limits established by international government bodies, demonstrated that there is a safe level of CBD that can be consumed as a dietary supplement, even if the specific recommended values vary within an acceptable range. Additionally, in June 2020, CRN also filed a Citizen Petition with FDA providing additional evidence of safety.[27]

CRN is directly aware of numerous companies that have met with FDA and shared unpublished data in their possession that support CBD's safety at levels relevant to the products they would market as dietary supplements. In addition, at least three companies have submitted their own dossiers of relevant safety evidence in connection with New Dietary Ingredient Notifications for CBD-containing ingredients:

- Irwin Naturals, NDI 1199[28]
- Charlotte's Web, NDI 1202[29]
- cbdMD safety dossier[30]

Further, numerous studies evaluating the toxicity of CBD that are published in peer-reviewed scientific journals are available for FDA's review. Most recent examples include a preclinical testing program conducted on hemp-derived CBD isolate. Results of the studies in this testing program showed that:

- CBD was well tolerated at the studied dose levels following repeated oral exposure[31]
- Levels at which no adverse effects were observed were identified for reproductive and developmental toxicity[32]

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[25] https://www.crnusa.org/sites/default/files/pdfs/comments-pdfs/CRN-Comments_FDA-Scientific-Data-Cannabis-Cannabis-Derived-Compounds-written-sub0719.pdf
[26] Comment from CRN to FDA regarding CBD submitted June 25, 2020. https://www.regulations.gov/comment/FDA-2019-N-1482-4364
[27] See CRN Citizen Petition to FDA regarding CBD submitted June 16, 2020, https://www.regulations.gov/document/FDA-2020-P-1582-0001
[28] https://www.regulations.gov/document/FDA-2021-S-0023-0050
[29] https://www.regulations.gov/document/FDA-2021-S-0023-0053
[30] This dossier is not publicly available but is referenced in a citizen petition submitted by the Natural Products Association to FDA regarding CBD. https://www.regulations.gov/document/FDA-2022-P-0600-0001
[31] Henderson RG, Lefever TW, Heintz MM, Trexler KR, Borghoff SJ, Bonn-Miller MO. Oral toxicity evaluation of cannabidiol. Food Chem Toxicol. 2023 Jun;176:113778. doi: 10.1016/j.fct.2023.113778.
[32] Henderson RG, Welsh BT, Rogers JM, Borghoff SJ, Trexler KR, Bonn-Miller MO, Lefever TW. Reproductive and developmental toxicity evaluation of cannabidiol. Food Chem Toxicol. 2023 Jun;176:113786. doi: 10.1016/j.fct.2023.113786.

- CBD is unlikely to pose a genotoxic hazard[33]

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

FDA needs to thoroughly review the totality of scientific evidence relevant to the safety of CBD and CBD-containing extracts that would be used in dietary supplements. Despite the plethora of safety data available to FDA, the agency continues to claim that adequate safety evidence is lacking, while not appreciating that the safety profile of CBD-containing dietary supplements would be different than much higher-dosed approved drug products, as well as the body of evidence on the safety of CBD-containing hemp extracts.

In a recently published review article on the oral toxicity of CBD, FDA scientists place undue weight on the Epidiolex dataset and trivialize evidence that examines lower dosages of CBD.[34] "The dose makes the poison"[7] is the fundamental principle of toxicology. In essence, it means that all substances can be toxic depending on the level of exposure. Without considering the level of exposure, conclusions that a substance "raises safety concerns" are not meaningful. Considering that the vast majority of the data cited in the review article has been available for FDA's evaluation for years, it is unclear why the authors did not conduct a risk assessment. The Agency has had ample access to data and time to utilize the available data to determine a safe level of exposure, as has already been done by other government bodies.

At the very least, the authors of the review article could have provided context to the data on CBD that raise safety concerns, in particular, the doses used in the identified studies. For example, the doses used in the clinical studies on Epidiolex (equivalent to 900 mg/day in adults) are far higher—*actually on a magnitude or 20 or more times higher*—than the range of levels that would be used in dietary supplements. Identifying potential hazards without consideration of exposure levels does not serve public health interests.

Further, they ignore the body of evidence of the safety of CBD-containing hemp extracts that have been developed for dietary supplement use. Industry stakeholders have responded to FDA's call for scientific evidence on the safety of CBD by investing in research on their ingredients, which encompass a range of CBD-containing hemp extracts, as well as CBD isolate. This research, conducted in accordance with regulatory test guidelines, provides evidence to support the safe use of various CBD-containing ingredients for their intended uses. By not considering the totality of relevant evidence, FDA's approach to assessing the safety of CBD is incomplete and therefore does not provide meaningful information to consumers and industry.

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

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[33] Henderson RG, Welsh BT, Trexler KR, Bonn-Miller MO, Lefever TW. Genotoxicity evaluation of cannabidiol. Regul Toxicol Pharmacol. 2023 Aug;142:105425. doi: 10.1016/j.yrtph.2023.105425.

[34] Gingrich, J., Choudhuri, S., Cournoyer, P., Downey, J., Muldoon Jacobs, K. Review of the oral toxicity of cannabidiol (CBD). April 2023:113799. doi: https://doi.org/10.1016/j.fct.2023.113799

[7] Common paraphrase of Paracelsus: "All things are poison, and nothing is without poison; the dosage alone makes it so a thing is not a poison."

The regulatory framework for dietary supplements provides ample tools by which FDA balance consumer access to CBD products with consumer safety. DSHEA gives FDA authority in these areas:

- ✓ Good Manufacturing Practices specific to dietary supplements allows FDA to prevent the introduction of contaminants like heavy metals, pathogens, or solvents in the finished products.
- ✓ Mandatory recall authority (as dietary supplements are regulated as food, they are subject to the mandatory recall authority provided to FDA for food) would be available for unsafe CBD containing supplements.
- ✓ A safety standard for the removal of an unsafe ingredient already exists.
- ✓ New Dietary Ingredient notifications provide a process for bringing new ingredients, like CBD, to market under FDA oversight.
- ✓ Dietary supplements are subject to serious adverse event reporting for health-related incidents, (all adverse event reports, whether serious or not, must be reviewed and maintained by the manufacturer for 6 years).
- ✓ Dietary supplement facilities must register with FDA every two years.
- ✓ DSHEA provides oversight of labeling: (e.g., use of a mandatory Supplement Facts box, complete listing of ingredients, requirements that label claims must be truthful, supported by evidence and cannot claim to cure, mitigate, prevent, or treat a disease, a required disclaimer for supplements making structure/function claims).
- ✓ Content limits per serving – dietary supplements may not present "a significant or unreasonable risk of illness or injury under…conditions of use recommended or suggested in labeling"[35] and FDA has precedent of imposing maximum serving levels on specific ingredients.

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?

The hazards associated with CBD were identified largely from research on Epidiolex, as well as some older animal studies on CBD isolate. To determine risk of CBD-containing dietary supplements, the levels of exposure that may raise safety concerns relative to levels that would be consumed from dietary supplement use, as well as the body of evidence on the safety of CBD-containing hemp extracts must be considered. As described in our response to Question 11, the available research provides evidence to support the safe use of various CBD-containing ingredients for their intended uses.

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?

[35] 21 U.S.C. § 342(f), https://www.law.cornell.edu/uscode/text/21/342

While the data on Epidiolex should be reviewed as part of the totality of evidence on CBD, FDA must consider the doses used in the Epidiolex studies, in particular, the clinical studies, in comparison to the levels of exposure that would be consumed from dietary supplement use. As indicated in our response to Question 12, the doses used in the clinical studies on Epidiolex (equivalent to 900 mg/day in adults) are 20 or more times higher than the range of levels that would be used in dietary supplements. Unfortunately, the agency has placed undue weight on the Epidiolex dataset and trivialized evidence that examines lower, more relevant, doses. FDA has access to a range of safety data that is relevant to the ingredients intended for use in dietary supplements at levels that would be commonly used in supplement products. Studies have been published in peer-reviewed literature, submitted to the public docket that FDA opened to facilitate submission of CBD data, or shared directly with the Agency. However, FDA has repeatedly disregarded this evidence, continuing to rely heavily on safety concerns related to high dosage Epidiolex. FDA must recognize that the safety profile of CBD-containing dietary supplements would be different than much higher-doses approved drug 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?

If FDA determines that it is necessary to establish a maximum allowable safe level of CBD in individual dosages of dietary supplements, it has authority to create and enforce such maximum limits under DSHEA for dietary supplements. A dietary supplement may not present "a significant or unreasonable risk of illness or injury under…conditions of use recommended or suggested in labeling."[36] Prior to the FDA's eventual removal of ephedra entirely from the dietary supplement marketplace in 2004, it established a maximum level of 25 mg per serving. While industry did mount a challenge to FDA's rationale and evidentiary basis for the level, there was no question that DSHEA allowed FDA to set such limits if there was a public health objective to be served.

Additionally, as CBD would be an NDI, potential marketers of CBD would be required to submit an NDI notification to FDA and demonstrate their products would "reasonably be expected to be safe." As part of that review, FDA could establish a maximum safe level of CBD as a qualification to receive a non-objection letter. DSHEA expressly states that a dietary supplement is adulterated if it contains "a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."[37]

[36] 21 U.S.C. § 342(f), https://www.law.cornell.edu/uscode/text/21/342.
[37] 21 U.S.C. § 342(f)(1)(B).

This process of establishing an upper safe level would be preferable to conducting a Health Hazard Assessment, as has been proposed by other interested parties because the NDI process allows for flexibility as the usage history of CBD continues to evolve. A relatively low upper safe level for CBD today might be replaced with a higher level over time as even more safety evidence and actual use data become available.

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?

Questions 17, 18, and 19 all relate to the regulation and safety of other ingredients combined with cannabinoids. The current dietary supplement framework already accounts for the appropriateness and safety of ingredient combinations. Any ingredient combined with hemp-derived cannabinoids must first be one of the type of dietary ingredients listed under 21 U.S.C. 321(ff)(1) (this provision specifically allows for combination of dietary ingredients) or, if a non-dietary ingredient, must meet the same safety requirements as substances added to conventional foods. The safety of a combination of ingredients will be considered under the standard described in our response to Question 5 (i.e., that the dietary supplement does not "present a significant or unreasonable risk of illness or injury").

FDA enforcement, processes, and draft guidance take into account the safety of combining ingredients. For example, FDA's 2016 draft guidance for submitting new dietary ingredient notifications (NDIN) contains a number of examples and recommendations for how companies should support the safety of ingredient combinations and include safety information in an NDIN. FDA prioritizing finalizing this long overdue guidance would be more supportive of supplement safety, including supplements containing hemp-derived regulatory cannabinoids, than the creation of a new regulatory framework specific only to CBD and other cannabinoids.

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?

If FDA wants to establish current GMP regulations for products containing CBD, it need only look as far as the GMPs for dietary supplements as a model.[38] The comprehensive requirements of Part 111 for dietary supplements cover such topics as:

- Required sanitation standards for the grounds and facilities
- Designated quality control personnel
- Specified for incoming components (ingredients) and testing to confirm their potency, purity, strength and composition
- Specifications for the finished product
- Master manufacturing records
- Batch production records
- Separate requirements for packaging and labeling of finished products
- Requirements for returning products
- Requirements for receiving and managing consumer complaints

If FDA needs to impose additional GMP requirements specific to CBD, that could be more efficiently accomplished with amendments to Part 111 specific to CBD rather than starting over and creating an entirely new set of cGMPs just for CBD.

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?

Supplement companies may seek third-party verification of their supplement products for a variety of reasons including demonstrating that products meet retailer quality standards or are used in marketing material to emphasize to consumers that a neutral third-party has reviewed the quality of the product. Various organizations exist to provide such third-party verification, among them United States Pharmacopeia (USP), the National Science Foundation (NSF), and – specific to hemp-derived cannabinoids – the U.S. Hemp Authority. Congress could provide direction to FDA to continue to work with these third parties to develop standards and then use third party verifications to prioritize auditing products that do not meet the standards for a third-party seal.

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.

Dietary supplements are permitted to make structure function claims, which describe "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient."[39] Dietary supplements may not make disease claims, which are reserved for drugs. These would include any claim

[38] See 21 CFR Part 111.
[39] 21 U.S.C. § 343(r)(6).

to "diagnose, mitigate, treat, cure, or prevent, a specific disease or class of disease."[40] A dietary supplement is misbranded if its labeling "is false or misleading in any particular."[41] Moreover, the statute permits health-related claims in labeling only if "the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading."[42] And it further requires that such statements be accompanied with prescribed disclaimers:

> *This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.*[43]

If properly enforced, these requirements would provide appropriate parameters for allowable claims for CBD outside of the context of drug claims. (e.g., "Promotes relaxation," "Relieves daily stress," "Aids with occasional sleeplessness.")

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?

Questions 23 to 25 ask about CBD product labeling, such as use of symbols, benefits or drawbacks of additional or substitute standardized label information, and specific labeling for special populations (e.g., children, pregnant and lactating women, etc.). CRN cautions against deviating from the current use of the uniform standardized supplement labeling framework. Consumers are used to seeing supplement products labeled in a specific and uniform manner. Key information about a supplement must be provided in a specific format and location on a product label – ensuring consumers know exactly where to look on any given package for key information such as the type of ingredients, amounts of dietary ingredients, their sources, etc.

Further, as noted above in our answer to Question 5, the determination of whether a supplement is safe must take into consideration any conditions of use recommended or suggested in labeling. Thus, the supplement labeling framework already takes into account the use of warnings for special populations and other conditions. In the case of CBD, many products on the market already bear label warnings that users should consult with healthcare professionals before use, and cautionary statements against use by pregnant/lactating women and those under the age of 18. A search of the Supplement Online Wellness Library (OWL) shows some examples of products that contain such label statements (e.g. vitafusion™ CBD Full Spectrum Hemp Extract Chill Mood and Happy Lane Gummies - 25 mg Cherry Jubilee 1 pk 10 ct).

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[40] 21 U.S.C. § 343(r).
[41] 21 U.S.C. § 343(a).
[42] 21 U.S.C. § 343(r)(6)(B).
[43] 21 U.S.C. § 343(r)(6)(C).

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?

Along with testing requirements, CRN member companies are committed to transparency in the dietary supplement marketplace. In fact, the organization is a longtime supporter of FDA's calls for a federal dietary supplement listing program as a critical tool for the agency, retailers, and consumers. We support the agency's authority to increase consumer information and are open to conversations about labeling standards for potential intoxicating content.

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.

As a preliminary matter, if the appreciable amounts of THC (and any other intoxicating constituents) were required to be removed from any CBD-containing dietary supplements, it would be incumbent on FDA to demonstrate that the CBD products held any unique appeal to those under 18 years old, or that these products present a significant health risk from ingestion by those under 18. How is a CBD-containing product particularly enticing compared to other botanical dietary supplements? FDA does not generally restrict product features for other dietary supplements and the industry has not experienced remarkable numbers of adverse events associated with other dietary supplements.

However, to prevent CBD products from appealing to or being ingested by children, specific restrictions could be applied to their labeling and packaging if necessary. Precedents from other dietary supplements can inform these restrictions:

> **Labeling Requirements:** Clear and concise labeling should be enforced, providing accurate information about the product's contents, usage, and potential risks. Labels could also prominently display cautionary statements like "This product is not intended for those under 18 years old," or "Not intended for children." Many current dietary supplements contain similar advisories that caution the product is suitable for minors. FDA has authority to require such warning statements to assure the product does not present "a significant or unreasonable risk of illness or injury *under the conditions of use recommended or suggested in labeling*."[44]
>
> **Packaging Restrictions:** Mandatory child-resistant packaging (CRP) could be required for all CBD products to reduce their accidental ingestion by children. FDA could also work with the Consumer Product Safety Commission (CPSC) to implement such requirements as similar ones have been imposed on iron-containing dietary supplements.[45] Many supplement manufacturers already voluntarily provide CRP on their products beyond iron as an overabundance of caution

[44] 21 USC 342(f)(1)A).
[45] Poison Prevention Packaging Act, codified at 15 U.S.C. §§ 1471-1477. *See also* regulations specific to iron-containing dietary supplements at 16 CFR 1700.14(a)(13).

for children—similar industry self-regulation could be expected here, both as demonstrations of self-policing and because of the heightened litigation environment which invites enterprising litigants to target this industry. In addition, FDA could work with industry to set limits on package size and total CBD content in a single package, as well as individual dosing packaging (e.g., blister packs) if it is determined that such cautionary measures are appropriate.

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?

Packaging and measuring devices to easily divide a product with multiple servings into single servings (e.g., blister packs, droppers) are already used for various dietary supplement products and can be implemented for CBD-containing dietary supplements.