

March 10, 2021

Dear Senator or Representative:

The undersigned consumer organizations and experts urge Congress to reject [HR 841](#)¹ and to similarly reject any attempts to force federal regulators to categorically and immediately legalize hemp-derived substances for use in dietary supplements or food products.

The Food and Drug Administration (FDA) has been clear that cannabidiol (CBD) cannot be used in dietary supplements because CBD is currently an approved drug and it is not generally recognized as safe, or “GRAS.”² Until the FDA is able to determine how to ensure that products containing CBD and/or other cannabinoids are safe for consumers to use, it cannot and should not waive legal requirements that prohibit any approved drug, including CBD, from being included in dietary supplements.

Consumers have a right to safe and appropriately labeled consumer products. For this reason, the FDA is currently evaluating the safety implications of CBD use in foods and supplements.³ The agency also has created a high-level internal agency working group to explore potential pathways for dietary supplements and/or conventional foods containing CBD to be lawfully marketed,⁴ held public meetings to determine the safety implications of CBD use,⁵ and drafted CBD enforcement policy guidance that was under the Office of Management and Budget (OMB) review.⁶ That policy was recently withdrawn due to President Biden’s regulatory freeze.⁷

We strongly oppose any bill to force the FDA to allow cannabidiol (CBD) and “*any* other ingredient derived from hemp” to be used in dietary supplements as a dietary ingredient within set period of time from enactment.⁸ Such a measure would cut short the FDA’s current efforts, create an unsafe CBD market, and irreparably politicize the FDA’s scientific oversight of the food and drug supply.

It is clear that Congress is not the right evaluator of the safety of consumer products. A political decision to legislatively override a careful and scientific evaluation of CBD safety would create a terrible precedent, and one that could pave the way for similar legislative overrides of FDA’s role on a range of recreational drugs.

If these types of bills are enacted, more well-funded profiteers would inevitably barrage Congress with requests for their chosen products to be given carte blanche, bypassing oversight designed to assure safety and quality. For their part, consumers would wrongly believe that these products have been evaluated while potentially being put at risk. We warned about these very risks in our previous letter on CBD, which we sent in June 2020.⁹

These types of bills would open a Pandora’s box of regulatory headaches related to products made from the hundreds of other hemp-derived ingredients, including delta-9-tetrahydrocannabinol (THC)—a psycho-active cannabinoid—and more than 100 compounds chemically related to THC.¹⁰ Many of these substances are not well studied—or studied at all—for safety or effectiveness.

Currently, the 2018 Farm Bill decriminalizes compounds derived from hemp if the compound contains no more than 0.3 percent THC on a dry weight basis.¹¹ However, HR 841 legalizes all compounds derived from hemp, which includes THC, in dietary supplements without providing any limitations, such as concentration levels or dosage for CBD or other cannabinoids, in the final product. Indeed, CBD products on the market have been tested to reveal levels of THC well above 0.3 percent.¹²

Legislative measures such as HR 841 typically allow the FDA 90 days from enactment to adequately assess the impact of adding likely hundreds of hemp-derived chemicals on our nation's health before CBD becomes widely available for general consumption. Thereafter, the agency would have to be prepared to monitor the safety of these products once on the market, assess their impact, and take action against unsafe and misleading products and marketing practices.

Yet, the FDA is unable to accomplish these goals for the tens of thousands of dietary supplements that are already on the market. The limited authorities given to the FDA by the Dietary Supplement Health and Education Act of 1994 (DSHEA) makes the dietary supplement marketplace a "Wild West."¹³ Simply legalizing hundreds of additional hemp-derived ingredients—by Congressional fiat—without providing additional critical authorities to the agency will not make hemp-derived supplements or other products safe for consumers.

Instead of forcing the agency to create a pathway for hemp-based supplements, we urge Congress to provide the FDA and the Department of Health and Human Services (HHS) with the direction, resources, authorities, and time needed to better regulate hemp-based supplements and the supplements marketplace in general.

1. The FDA is currently unable to regulate the current dietary supplement marketplace and cannot be expected to safely regulate the onslaught of hemp-based supplements.

Dietary supplements are related to an estimated 23,000 emergency room visits per year.¹⁴ In 2015, adverse-event reports (AERs) submitted to the FDA describe at least 2,100 supplement incidents involving serious outcomes, including life-threatening illnesses and deaths.¹⁵

Lowell Schiller, the FDA's former Principal Associate Commissioner for Policy, recently noted that the FDA does not currently have a systematic way to know when a new supplement is introduced, nor can it determine how many products contain any given ingredient. The FDA also does not know how to capture market trends to anticipate and adapt to new areas of risk or effectively prioritize agency resources.¹⁶

On its website, the FDA admits it can conduct safety testing only for a small fraction of the thousands of dangerous supplements currently on the market,¹⁷ highlights that supplements are increasingly tainted with hidden chemicals and drugs,¹⁸ and warns that they frequently are marketed with unsubstantiated treatment claims, including for diseases such as COVID-19.¹⁹ Given the agency's inability to cope with the existing marketplace, there is no reason to believe that hemp-based supplements would be safe to consume if HR 841 is enacted.

At a minimum, any bill on hemp-derived supplements should be limited to hemp-derived CBD in supplements, and not all hemp-derived cannabinoids, as the safety profile of these other substances is not well understood and has not been studied. Moreover, any new measure should require that manufacturers and distributors establish the safety of a compound through new dietary ingredient notifications (NDINs) and establish limits on the amount of CBD per day and dose. Lastly, any bill should clearly authorize the FDA set maximum levels of CBD (and any cannabinoid, including but not limited to CBD) in products ranging from cosmetics to pet food.²⁰

Yet even these changes would only function as bare patches over a chasm of consumer safety concerns. Adding hundreds of hemp-derived ingredients to the supplement marketplace without first addressing numerous gaps in oversight would continue to overstretch the FDA's limited resources and make the dietary supplement marketplace more dangerous for consumers. Some of the gaps that must be addressed include:

1. Loopholes in premarket safety review: The “generally recognized as safe loophole” (GRAS) loophole allows supplement manufacturers to secretly self-certify that a new dietary ingredient is safe without filing a new dietary ingredient notice (NDIN), informing the FDA that a new ingredient is entering the market, or submitting any safety data to the FDA.²¹ Currently, the FDA asserts that CBD and THC are ineligible for secret GRAS determinations.²² However, HR 841 would potentially allow manufacturers to add these and hundreds of other hemp-based ingredients to supplements without FDA knowledge. Supplement manufacturers could also potentially use the GRAS loophole to chemically alter hemp-derived ingredients for supplement use without informing the FDA.
2. Lack of marketplace transparency: Supplement manufacturers are not required to register or inform the FDA of the supplements they sell. The FDA, thus, has no way of monitoring the supplements and ingredients that are being sold, nor can it measure in any active sense which dietary supplements are unsafe. The FDA would simply be unable to determine either the safety of, or impact on, consumers of hemp-derived supplements.
3. Lack of enforcement resources and authorities: The enforcement office with authority over supplements at the FDA is simply insufficient to address the large and growing supplement marketplace with an estimated 50,000 or more products.²³ The agency is already unable to monitor and test high-risk supplements commonly tainted with drugs and other dangerous chemicals.²⁴ Even when unsafe supplements are identified by the FDA, many bad actors will simply rebrand and reformulate their products after receiving a warning letter from the FDA, thus avoiding any future enforcement actions for repeated offenses. The FDA also has limited authorities to recall dangerous supplements and limited resources to conduct enforcement actions against unsafe supplements. Once unsafe ingredients are on the market, it is also far too difficult for the FDA to remove them. That is one reason ephedra remains the only example of a supplement FDA has fully removed from the market.²⁵

2. Many Hemp-based dietary supplement companies market their products irresponsibly: simply forcing the FDA to legalize such products will not address these hazards.

Manufacturers of hemp-based supplements today can market the benefits of THC in their product, claim erroneously that products are regulated by the FDA, market their supplements illegally to treat or prevent disease, and include levels of CBD and THC in products that differ from the labeling. Moreover, some products are adulterated with dangerous synthetic or other drugs.

Consider the following:

- **Mislabeling is common especially regarding THC presence:** The FDA’s July 2020 report to Congress found that many of the CBD and hemp supplements tested were mislabeled and contained less or more CBD than was advertised.²⁶
 - THC levels in the products tested ranged from below the quantifiable limit to 3.1 mg/serving, with 72 products (49 percent) found to contain THC or THCA (tetrahydrocannabinolic acid-A) at concentrations above the quantifiable limit. Testing of cosmetic products revealed that of the 41 products tested containing CBD, 12 also contained THC, although the products did not indicate the presence of THC.²⁷
 - 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.²⁸
 - For the nine samples that did not contain CBD, seven either did not indicate CBD or clearly indicated “zero CBD” on the label. Two products that listed CBD on the label were not found to contain CBD.²⁹
- **Adulteration is prevalent:** Ingredients not listed on product labels, including synthetic cannabinoids and dangerous contaminants, have been identified in CBD products in studies.³⁰
- **Misleading and illegal disease and treatment claims are common:** A slew of CBD companies have already advertised their products’ benefits in treating and preventing diseases.³¹ Since 2017, the FDA has issued at least 26 warnings letters to CBD companies that claim to treat or prevent numerous ailments,³² such as, COVID-19,³³ opioid withdrawal,³⁴ teething and ear pain in infants,³⁵ autism,³⁶ ADHD,³⁷ Parkinson’s and Alzheimer’s disease,³⁸ breast cancer,³⁹ diabetes,⁴⁰ and pain relief.⁴¹
- **Some products are inappropriately marketed to vulnerable populations such as children and pregnant people:** CBD supplements are marketed as Halloween and holiday gummy bears⁴² and treatments for ailments associated with pregnancy.⁴³ However, limited research has been conducted in the long-term effects of CBD (and/or improperly labeled CBD) on development in these populations.

- **Misleading claims, even from leading brands, are used to promote THC in CBD supplements:** For example, Vitamin Shoppe, a major supplement retailer with over 780 brick-and-mortar stores,⁴⁴ advertises the health benefits of the THC in its full-spectrum CBD supplements.⁴⁵ The company attempts to reassure consumers that the THC in its CBD products is legal by falsely claiming that “FDA regulations” currently allow CBD in dietary supplements if they contain 0.3 percent or less of THC (while of course there is no such regulation).⁴⁶

3. *Hemp-based supplements can only be regulated safely if the FDA is provided with additional resources, time, and authorities to address regulatory gaps.*

Both cannabinoid-specific and generally applicable steps are needed to prevent bad actors from entering the hemp-based supplement marketplace and to ensure consumer safety. Simply declaring hemp-derived ingredients legal for use in dietary supplements will not make them safe.

Instead, Congress should provide additional authorities, time, and resources to ensure that hemp-based ingredients and dietary supplements in general are safely regulated. **To support these efforts and expedite the FDA’s policymaking on hemp-based supplements, we recommend that Congress direct the FDA to:**

- Publish and finalize strong guidance indicating that the agency will use its temporary enforcement discretion⁴⁷ to focus on mitigating specific CBD hazards and protecting vulnerable populations, including by prioritizing:
 1. Products bearing health claims, especially for: serious or life-threatening diseases for which FDA-approved alternatives are available, those that raise the possibility of serious side effects, or those that pose a hazard to vulnerable populations, including children and pregnant people;
 2. Products that appeal to, or that are marketed for, children and youth;
 3. Products containing high doses of either CBD or THC, products with higher concentrations than labeled, and CBD products that contain unlabeled THC; and
 4. Products found to be mislabeled or contaminated, particularly with FDA-approved drugs, synthetic cannabinoids, heavy metals, dangerous mold, high levels of pesticide residues, other dangerous chemicals, or pathogens.
- Publish a comprehensive plan for CBD and other cannabinoids covering food, supplements, drugs, and cosmetics.
- Establish an inter-agency working group with the U.S. Consumer Product Safety Commission (CPSC) to address risks in consumer products from hemp-derived substances.

Moreover, as described in the 2021 Appropriations Bill’s Committee Report, Congress should provide the FDA with \$5 million in dedicated funds to regulate the cannabinoid dietary supplement marketplace, to include reviewing product applications, inspections, enforcement, targeted research for cannabis-derived and other substances, and a notification system for hemp-derived ingredients.⁴⁸

As described in the report, stakeholders should be required to notify the FDA of CBD use in products. We recommend that these notifications should, at the very least, include safety studies and determinations. While developing these regulations, Congress should also direct the agency to issue an interim policy on enforcement for hemp-derived products as we describe above.⁴⁹ The FDA should ensure that any future regulatory activity does not discourage the development of new drugs.⁵⁰

4. Congress should enact comprehensive reform legislation to ensure that all dietary supplements are safe for consumers.

As hemp-based supplements exist within the dietary supplement marketplace, creating a completely new regulatory framework for hemp-based supplements would create unnecessary complexity in the market, increase FDA's regulatory burden, and be yet another barrier for entry. Therefore, in addition to the policies above, we recommend that Congress authorize, direct, and fund the FDA to make the following comprehensive reforms for all dietary supplements:

- **Require mandatory product listing and registration:** The FDA should require mandatory product listing and registration so that it can track dangerous products and repeat offenders, identify hazards in dietary supplements, and anticipate safety issues.
- **Close the GRAS loophole:** The FDA should be required to revise its guidance documents and rules to prohibit supplement companies from using the GRAS loophole to secretly self-affirm that new ingredients and uses are safe without FDA review. A New Dietary Ingredient review (NDI) should be required for every novel ingredient and condition of use (within precise specifications), and the FDA should be directed to revise, by a certain date, its guidance and rules to strengthen the NDI review process.
- **Bolster adverse events reporting:** Supplement companies should be required to report all adverse events linked to their products by having to report all events, and not merely those that they self-designate to be “serious.”
- **Premarket review of known dangerous products:** The FDA should require specific pre-market review and more post-market surveillance of categories of supplements known to pose heightened risk because they are commonly tainted with drugs (*e.g.*, weight-loss, sexual enhancement, cannabinoid, and workout supplements) or those marketed to vulnerable populations, including children and pregnant people.
- **Require labeling of supplement-drug interaction warnings:** The FDA should require warning labels on products identifying known interactions with prescription or OTC medications.
- **Allocate additional resources:** The dietary supplement division is under-resourced and cannot keep pace with the large numbers of producers and products. Its budget should be doubled.
- **Strengthen enforcement:** Congress should ask the FDA to revise the Regulatory Procedures Manual to allow the agency to issue increased penalties for repeated violations when company has rebranded or reformulated its supplements to avoid enforcement.

- **Authorize shared enforcement:** To help increase local oversight and enforcement, State Attorney Generals should have the authority to file civil enforcement actions related to DSHEA violations, in coordination with the FDA and Federal Trade Commission.
- **Provide recall authority:** The FDA should have recall authority over supplements tainted with prescription or other drugs.
- **Authorize criminal penalties:** The FDA should have the authority to pursue criminal penalties for a failure to recall hazardous supplements subject to a recall notice.
- **Accurately define dietary supplements:** Currently, under DSHEA, products that do not contain at least one “dietary ingredient” do not meet the definition of dietary supplements, even when they are marketed as supplements and contain drugs or other dangerous substances.⁵¹ In these cases, the FDA cannot use its dietary supplement authorities to regulate until after the agency can make a determination that the product contains a dietary ingredient.⁵² The product may fall under FDA’s authority to regulate drugs. However, that authority may not be clear until after determining whether the product contains drugs or makes a disease and treatment claim. This process can involve complex scientific analysis, and it can be both resource-intensive and time-consuming.⁵³ As a result, many dangerous supplements may fall through gaps in FDA’s oversight. To clarify FDA’s enforcement authorities over supplements, Congress should define dietary supplements as “adulterated” if they contain substances that are illegal to include in a supplement and are marketed as a supplement, regardless of whether they include a “dietary ingredient.”

5. Conclusion

We strongly urge the Congress to take this moment to actually fix the oversight of dietary supplements and ensure the products in the marketplace now and that may come to market in the future, are accurately labeled, not misleadingly marketed, and safe for consumers. Now is the time to address the need for DSHEA 2.0.

Should Congress fail to create meaningful reform or provide the FDA with the minimum tools needed to safely regulate CBD, Congress should not pass any legislation that bypasses what little resources and authorities the FDA has by forcing an arbitrarily short timetable for approval.

If you have questions or would like further information, please contact Laura MacCleery, Director of Strategy and Program, CSPI, at 202-489-7147 or lmaccleery@cspinet.org.

Sincerely,

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Notes:

¹ HR 841. *Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2021*. <https://www.congress.gov/bill/117th-congress/house-bill/841/text>. Accessed February 23, 2021.

² U.S. Food and Drug Administration (FDA). *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*. November 1, 2020. <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>. Accessed December 14, 2020.

³ E.g., 84 Fed. Reg. 12969 (April 3, 2019).

⁴ FDA. *FDA Statement: Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to advance agency's continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products*. April 02, 2019. <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation>. Accessed November 23, 2020.

⁵ E.g., FDA. *Conference: Scientific Conference: CBD and Other Cannabinoids: Sex and Gender Differences in Use and Responses*. November 19, 2020. <https://www.fda.gov/science-research/womens-health-research/scientific-conference-cbd-and-other-cannabinoids-sex-and-gender-differences-use-and-responses>. Accessed November 23, 2020; FDA. *Public Hearing: Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing*. May 31, 2019. <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds>. Accessed November 23, 2020.

⁶ JD Supra. *FDA Sends CBD Enforcement Policy to OMB, Issues Cannabis Clinical Research Draft Guidance, and Submits CBD Testing Report to Congress*. July 27, 2020. <https://www.jdsupra.com/legalnews/fda-sends-cbd-enforcement-policy-to-omb-22125/>. Accessed March 4, 2021.

⁷ Presidential Actions. *Regulatory Freeze Pending Review*. January 20, 2021. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/>. Accessed January 26, 2021.

⁸ HR 841; H.R. 8179 (emphasis added).

⁹ Center for Science in the Public Interest (CSPI). *Letter to Congress June 17, 2020 re: CBD*. June 17, 2020. <https://cspinet.org/resource/letter-congress-june-17-2020-re-cbd>. Accessed December 2, 2020.

¹⁰ 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.

¹¹ FDA. *Hemp Production and the Farm Bill*. July 25, 2019. <https://www.fda.gov/news-events/congressional-testimony/hemp-production-and-2018-farm-bill-07252019>. Accessed December 14, 2020.

¹² Bonn-Miller MO, et al. Labeling Accuracy of Cannabidiol Extracts Sold Online. *JAMA*.2017;318(17):1708-1709.

¹³ 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 December 2, 2020 (“In general, the FDA says, a manufacturer ‘does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products.’ As a result, [Dr. Peter] Lurie said, the supplement market is like the ‘Wild West,’ and ‘the small dietary supplement office at FDA can’t possibly keep up.’”).

¹⁴ Andrew I. Geller, et al., “Emergency Department Visits for Adverse Events Related to Dietary Supplements,” *The New England Journal of Medicine*, Oct. 15, 2015.

¹⁵ Jennifer Weeks, “Dietary Supplements,” *CQ Researcher*, Oct. 30, 2015, Vol. 25 No. 39, at 916.

¹⁶ FDA. *Remarks by Lowell Schiller, JD at the Council for Responsible Nutrition Conference - 11/7/2019*. November 7, 2019. https://web.archive.org/web/20191213060131mp_/https://www.fda.gov/news-events/speeches-fda-officials/remarks-lowell-schiller-jd-council-responsible-nutrition-conference-1172019-11072019. Accessed November 24, 2020.

¹⁷ *E.g.*, on its list of Tainted Products Marketed as Dietary Supplements, the FDA states, “This list only includes a **small fraction of the potentially hazardous products** with hidden ingredients marketed to consumers on the internet and in retail establishments. **FDA is unable to test and identify all products marketed as dietary supplements on the market that have potentially harmful hidden ingredients**. Even if a product is not included in this list, **consumers should exercise caution before using certain products**. To learn more about how to reduce your risk of encountering a product marketed as a dietary supplement with a hidden ingredient please visit FDA's Medication Health Fraud webpage linked above (emphasis added).” FDA. *Tainted Products Marketed as Dietary Supplements CDER*. October 13, 2020. https://www.accessdata.fda.gov/scripts/sda/sdnavigation.cfm?sd=tainted_supplements_cder. Accessed November 17, 2020.

¹⁸ *E.g.*, FDA *Tainted Sexual Enhancement Products*. November 24, 2020. <https://www.fda.gov/drugs/medication-health-fraud/tainted-sexual-enhancement-products>. Accessed December 7, 2020; FDA *Tainted Weight Loss Products*. November 24, 2020. <https://www.fda.gov/drugs/medication-health-fraud/tainted-weight-loss-products>. Accessed December 7, 2020; FDA; *Tainted Body Building Products*. December 13, 2018. <https://www.fda.gov/drugs/medication-health-fraud/tainted-body-building-products>. Accessed December 7, 2020; FDA. *Beware of Fraudulent Dietary Supplements*. March 15, 2011. <https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-dietary-supplements>. Accessed November 24, 2020.

¹⁹ *E.g.*, FDA. *Coronavirus Update: FDA and FTC Warn Seven Companies Selling Fraudulent Products that Claim to Treat or Prevent COVID-19*. March 09, 2020. <https://www.fda.gov/news-events/press-announcements/coronavirus-update-fda-and-ftc-warn-seven-companies-selling-fraudulent-products-claim-treat-or>. Accessed November 24, 2020.

²⁰ Natural Products Insider. *FDA, Congress differ on how CBD should be regulated in supplements*. November 24, 2020. <https://www.naturalproductsinsider.com/regulatory/fda-congress-differ-how-cbd-should-be-regulated-supplements>. Accessed December 7, 2020.

²¹ FDA. *Public Meeting to Discuss the Development of a List of Pre-DSHEA Dietary Ingredients*. P. 49. October 2017. Transcript available at <https://www.fda.gov/media/108452/download>. Accessed May 11, 2020; Nutritional Outlook. *FDA's Tave outlines obstacles to dietary supplement market enforcement at CRN's Virtual Conference*. October 16, 2020. <https://www.nutritionaloutlook.com/view/fda-s-tave-outlines-obstacles-to-dietary-supplement-market-enforcement-at-crn-s-virtual-conference>. Accessed December 2, 2020 (“Said Tave [director of FDA’s Office of Dietary Supplement Programs]: ‘We know that many dietary supplement firms choose to first introduce new ingredients into the food supply using the self-GRAS process, which does not require notification to FDA. As a result, we can’t just look at a product and assume it is out of compliance simply because there is no NDI notification, and that is a problem because Section 402(f) [of the Federal Food, Drug, and Cosmetic Act], which is the applicable adulteration provision, requires us to bear the burden of proof on each element of an evaluation.’”).

²² FDA. *FDA Regulation of Dietary Supplement & Conventional Food Products Containing Cannabis and Cannabis-Derived Compounds*. <https://www.fda.gov/media/131878/download>. Accessed November 23, 2020.

²³ *See*, Steve Tave. *Remarks at 2020 Dietary Supplements Regulatory Summit*. <https://web.unpa.com/events/2020-Dietary-Supplements-Regulatory-Summit-NEW-DATE-89/details>. Accessed November 16, 2020.

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- ²⁴ E.g., FDA. *Tainted Products Marketed as Dietary Supplements_CDER*. October 13, 2020. https://www.accessdata.fda.gov/scripts/sda/sdnavigation.cfm?sd=tainted_supplements_cder. Accessed November 17, 2020.
- ²⁵ 69 Fed. Reg. 6787 (February 11, 2004) at 6794. <https://www.federalregister.gov/d/04-2912/p-118>. Accessed March 4, 2021. (“We are using this rulemaking authority for dietary supplements containing ephedrine alkaloids because we are articulating a standard for unreasonable risk under 402(f)(1)(A) of the act **for the first time**...(emphasis added)”)
- ²⁶ 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.
- ²⁷ *Id.* at 6-7.
- ²⁸ *Id.*
- ²⁹ *Id.*
- ³⁰ 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.
- ³¹ 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.
- ³² A search for “CBD” on FDA’s “Warning Letters” webpage produces 26 warning letters with “Unapproved New Drugs” as its subject line. FDA. *Warning Letters*. February 19, 2021. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>. Accessed February 22, 2021; FDA. *Warning Letters and Test Results for Cannabidiol-Related Products*. December 22, 2020. <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>. Accessed February 22, 2021.
- ³³ 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.
- ³⁴ 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.
- ³⁵ 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.
- ³⁶ *Id.*
- ³⁷ *Id.*
- ³⁸ *Id.*

³⁹ 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.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *E.g.*, Bioreigns. Facebook Post October 28, 2020. <https://www.facebook.com/bioreigns/posts/1074574452958637>. Accessed November 30, 2020 (Facebook post has an image with the title “Halloween Trick or Treat” and includes CBD gummy bears); Bioreigns. Facebook Post November 29, 2020. <https://www.facebook.com/bioreigns/posts/1101523710263711>. Accessed December 2, 2020; Pure Kana. *What are CBD Lollipops?* <https://purekana.com/blogs/news/what-are-cbd-lollipops/>. Accessed December 9, 2020; Canna Kids. <https://cannakids.org/>. Accessed December 19, 2020.

⁴³ HEMPIKA. *Is it safe to use CBD while pregnant or breastfeeding?*. <https://hempika.com/cbd-for-pregnancy-and-breastfeeding/>. Accessed December 2, 2020 (“There are plenty of reasons why a woman might want to take CBD oil while pregnant or breastfeeding. Taking CBD oil or supplements has been shown to help alleviate some of the worst symptoms felt by pregnant mothers. CBD can help mitigate anxiety, postpartum depression, morning sickness, insomnia, and chronic pain, all of which are potential side effects of being pregnant or of recently giving birth.”).

⁴⁴ The Vitamin Shoppe. *About The Vitamin Shoppe*. <https://www.vitaminshoppe.com/u/about-vshoppe>. Accessed December 1, 2020.

⁴⁵ The Vitamin Shoppe. *The Difference Between Broad-Spectrum, Full-Spectrum, And Isolated CBD*. February 21, 2020. <https://whatsgood.vitaminshoppe.com/types-of-cbd-supplements/>, Accessed December 1, 2020 (“Combining CBD, THC, and these other natural compounds creates what’s known as the ‘entourage effect,’ says Titus. ‘The synergistic application of all the plant materials works better than just an isolated compound.’ In other words, these various compounds work together to achieve a greater effect in the body than one single compound alone. This makes full-spectrum CBD the most powerful (and desirable) option.”).

⁴⁶ *Id.* (“Yep, that means that products labeled “full-spectrum CBD” may also contain some THC, the psychoactive ingredient in cannabis associated with the high sensation marijuana causes. Don’t worry, though, [FDA regulations](#) require that CBD and other hemp products contain less than 0.3 percent THC, which will not get you high.”).

⁴⁷ This temporary enforcement discretion should be utilized until the FDA can establish a more robust regulatory framework as described later in this memo.

⁴⁸ US Senate Committee on Appropriations. *Explanatory Statement for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2021*. P. 111-112. <https://www.appropriations.senate.gov/imo/media/doc/AGRept.pdf>. Accessed November 17, 2020 (“Cannabis and Cannabis Derivatives.—As previously noted, the Committee provides \$5,000,000 to support regulatory activities, including developing policy, and for the FDA to continue to perform its existing regulatory responsibilities, including review of product applications, inspections, enforcement, and targeted research for cannabis-derived substances, such as cannabidiol [CBD]. Within 90 days of enactment of this Act, the FDA shall issue a policy of enforcement discretion with regard to certain products containing CBD meeting the definition of hemp as defined by section 297A of the Agricultural Marketing Act of 1964 (7 U.S.C. 1639). Such enforcement discretion shall be in effect until the FDA establishes a process for stakeholders to notify the FDA of use of CBD in products that include safety studies for intended use per product and makes a determination about such product. In addition, the FDA is encouraged to consider existing and ongoing medical research related to CBD that is being undertaken pursuant to an Investigational New Drug application in the development of a regulatory pathway for CBD in products under the jurisdiction of the FDA and to ensure that any future regulatory activity does not

discourage the development of new drugs. The Committee also encourages the FDA to partner with an academic institution to expand sampling studies of CBD products currently on the market.”).

⁴⁹ US Senate Committee on Appropriations. *Explanatory Statement for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2021*. P. 111-112.

<https://www.appropriations.senate.gov/imo/media/doc/AGRept.pdf>. Accessed November 17, 2020.

⁵⁰ *Id.*

⁵¹ Tave, Steve. *S. Tave Remarks – 2020 FDLI Food Advertising, Labeling, & Litigation Conference*.

Food, Drug, Law, Institute. September 22, 2020 (“But many of the ingredients that we have flagged do not qualify as dietary ingredients at all under the statute. One recent examples is tianeptine. And here’s where it can get really complicated and just plain weird. A product is not a dietary supplement under the statute unless it ‘contains one or more’ dietary ingredients. So because tianeptine is not a dietary ingredient, a single-ingredient product that contains only tianeptine does not contain one or more dietary ingredients, and therefore it isn’t a dietary supplement. Again, it might make drug claims and be subject to drug charges. But what if it doesn’t? On the other hand, if a product containing tianeptine has multiple ingredients, none of which are excluded drug ingredients, and at least one of them is a dietary ingredient – say, for example, a product containing only tianeptine and Vitamin C – then we can charge it as a dietary supplement that is adulterated because it contains an unsafe food additive, once we’ve determined that tianeptine is an unsafe food additive. So two otherwise identical products containing the same unlawful ingredient might be subject to completely different charging schemes, for reasons unrelated to the unlawful ingredient itself. While these issues might sound esoteric, they have tangible real-world consequences. The determination of whether an ingredient qualifies as a dietary ingredient is often far from straightforward. It can involve complex scientific analysis, and it can be both resource-intensive and time-consuming. The outcome of that inquiry might determine which of the applicable standards – dietary ingredient or food additive or even drug – we need to evaluate. And our decisions aren’t always accepted. In fact, we’re entering our seventh year of litigation about one of these determinations.”).

⁵² *Id.*

⁵³ *Id.*