



June 17, 2020

Dear Senator or Representative:

The undersigned consumer organizations write to again urge Congress to reject any attempts to force federal regulators to immediately legalize cannabidiol (CBD) use in dietary supplements and food products.

Adding CBD to hundreds of dietary supplements and foods presents completely new safety, health, and regulatory issues that must be adequately understood and addressed. While we understand that the Food and Drug Administration (FDA) is well underway with an evaluation of CBD use in foods and supplements,¹ its attention and limited resources were recently diverted to address the novel coronavirus pandemic. Forcing the FDA into rushed decisions and to prematurely implement major regulatory changes would result in an unsafe CBD market and distract the FDA from its current pandemic response and recovery efforts.

It is also clear that Congress is not the right evaluator of the safety of consumer products, and a political decision to legislatively override a careful and scientific evaluation of CBD safety would create terrible precedent. More well-funded profiteers would inevitably barrage Congress with requests for their chosen products to be given *carte blanche*, bypassing oversight that assures safety and quality. For their part, consumers would wrongly believe that products have been evaluated while potentially being put at risk.

For foods, cosmetics and medical uses, Congress should ensure that this critical job remains in the hands of the FDA, which should not be rushed to make a judgment about CBD that may impact the health and safety of millions of consumers. The agency needs additional time, resources, and authorities to adequately assess the science and unknown risks involved with adding CBD to the hundreds of foods and supplements consumed by Americans.

Concerns about potential safety issues related to CBD have been flagged by the FDA. The FDA Principal Deputy Commissioner, Amy Abernethy, M.D., Ph.D., noted in a statement from the agency in November 2019:

We remain concerned that some people wrongly think that the myriad of CBD products on the market, many of which are illegal, have been evaluated by the FDA and determined to be safe, or that trying CBD ‘can’t hurt.’ Aside from one prescription drug approved to treat two pediatric epilepsy disorders, these products have not been approved

by the FDA and we want to be clear that a number of questions remain regarding CBD's safety – including reports of products containing contaminants, such as pesticides and heavy metals – and there are real risks that need to be considered. We recognize the significant public interest in CBD and we must work together with stakeholders and industry to fill in the knowledge gaps about the science, safety and quality of many of these products.

The FDA has been clear in its public pronouncements that CBD is not “generally recognized as safe” or GRAS, and has issued warning letters against companies illegally marketing CBD products.² Our understanding is that a more developed agency evaluation of CBD is underway currently at the FDA, and has been delayed only by the need to divert resources to the novel coronavirus pandemic.

Rather than Commandeering the Agency's Scientific Evaluation Process, Congress Should Provide the Resources and Authority the Agency Needs to Address the Safety of Foods and Dietary Supplements

Given the potential health risks and these regulatory deficiencies, Congress should instead provide the agency additional authorities and resources to ensure that CBD-containing products—and all dietary supplements and food additives—are safe for consumption. These new authorities and resources should include:

- For dietary supplements, due to gaps in the FDA's general funding and authorities, it is clear that the agency currently lacks adequate legal authority to assure consumer safety and the consistency or quality of products containing CBD. We provide concrete policy steps below.
- For food uses, the FDA does have a process, but would need time to make a safety determination based on the evidence, and should still receive funding and resources to address its needs to improve the quality of its safety assessments. In addition, Congress should require the agency to update the scientific standards that the FDA applies, which do not adequately model exposure or account for vulnerable populations.
- The FDA should be encouraged to explore warnings if any approved both food and dietary supplements uses are the result of its evaluations, as well as take the steps outlined below.

The FDA Is Correct to Gather the Evidence on the Risks of CBD, including Adulteration and Serious Liver Toxicity at High Doses

Much is still unknown about the risks and safety of CBD and other cannabinoids. A recent analysis concluded that there is insufficient data to be able to reliably characterize CBD-specific risks, particularly for young children.³ In clinical trials for drugs to treat Lennox-Gaust syndrome, involving relatively high doses of CBD, adverse effects included diarrhea, somnolence, loss of appetite and increased levels of liver enzymes.⁴ Clinical trials for Epidiolex revealed that CBD doses of 10 to 20 milligrams per kilogram of body weight per day create a potential for liver injury.⁵

CBD products marketed in such doses, and in shapes well-known to appeal to children, are currently available for sale. Among many examples we found on-line, the company, Pure Relief, sells teddy bear-shaped CBD gummies with 10 mg of CBD per gummy and 900 mg CBD per unit of sale.⁶ Despite warnings by the FDA about the risks of CBD use during pregnancy,⁷ websites like Hempika tout the benefits of a range of CBD oil products for pregnant and breastfeeding people, suggesting without evidence that “[t]aking CBD oil or supplements has been shown to help alleviate some of the worst symptoms felt by pregnant mothers.”⁸

Mislabeling and adulteration are also common. Troublingly, many CBD products have been found to contain THC (tetrahydrocannabinol), a psycho-active cannabinoid, or other cannabinoids. Tests of 84 CBD products in 2016 found that 26% had CBD levels significantly higher than indicated on the label. Overall, 58 of the 84 products (69%) were inaccurately labeled, with higher or lower CBD concentrations. THC was detected at levels over 0.3% (with levels exceeding 6 mg/mL in one instance) in 18 of the 84 samples tested, and the THC content observed could be sufficient to produce intoxication or impairment, especially among children.⁹ The Marijuana Policy Project, which runs a campaign titled “Consume Responsibly,” urges inexperienced users to start with 5 mg of THC, noting that the effects of higher dosages to have proved too powerful for novice users and some users with smaller body types.¹⁰

Ingredients that are not listed on product labels, including synthetic cannabinoids and dangerous contaminants, have been identified in cannabis products in other studies.¹¹ Nine product samples purchased by investigators in Utah, labeled as CBD products, contained a synthetic cannabinoid, but no CBD.¹² An 8-year old boy who consumed CBD oil for epilepsy was sent to the hospital according to a case report, and a subsequent analysis revealed synthetic cannabinoids in the product alongside CBD.¹³

In a 2018 study, researchers analyzed nine CBD e-liquids which were used for electronic cigarettes and produced by one manufacturer.¹⁴ The study found unexpected detections of 5F-ADB (a street drug known as “K2” and “Spice”)¹⁵ in four of the products and dextromethorphan (a chemical found in many cough medications)¹⁶ in one of the products.¹⁷ Furthermore, because marijuana and hemp absorbs soil contaminants, CBD extracts and concentrates that are added to food can become more concentrated during processing.¹⁸

Congress Should Not Place Undue Political Pressure on the FDA’s Scientific Evaluation and Regulatory Considerations

Current FDA policy is that CBD is not legal for use in supplements and food because it was the subject of a drug application (the so-called “exclusion rule” or “IND exclusion rule”), and ultimately of an approved drug product.¹⁹ Under the law, the FDA may waive the exclusion rule at the agency’s discretion, but only after issuing a regulation following notice and comment and finding that the article would be lawful under the Federal Food, Drug, and Cosmetic Act.²⁰ Such a waiver, then, must be consistent with the broad purposes of the FDA to assure and improve public health and safety.

As a practical matter, development of such a waiver would require the FDA to develop a concrete, public-facing program to address each category of cannabis product within its

jurisdiction, to take steps to specifically mitigate their risks, and to enforce standards that, over time, bring conflicting state and local programs into alignment with applicable federal laws supporting consumer health and safety. Any bill or legislative language that would short-circuit this process by pressuring the agency to rapidly issue an enforcement discretion policy is ill-advised.

The agency has also clearly indicated that, regardless of the exclusion rule, it is “explor[ing] potential pathways for various types of CBD products to be lawfully marketed...and “work[ing] quickly to further clarify our regulatory approach for products containing cannabis and cannabis-derived compounds like CBD.”²¹ Thus the agency already has a process in place to consider the very issues Congress has in mind.

Legislative direction from Congress that would require the FDA to hastily create a pathway to legalization of CBD in foods and supplements is deeply problematic because the FDA currently lacks the needed authority and resources to effectively address the myriad issues that may arise from CBD use in supplements. Numerous improvements in the agency’s poor general oversight of supplements are needed to address such problems, including requirements for product listing and registration, improved quality controls, and more robust enforcement resources. We suggest necessary improvements below.

In addition, the GRAS loophole for food substances has been permitted, over time, to allow substances in both food and dietary supplements to utterly evade safety review by the FDA. Food companies routinely make use of the so-called “secret GRAS” process, which allows companies to self-determine that a substance is “generally recognized as safe,” or GRAS, and use it in food without telling the FDA.²² This secret GRAS policy is currently the subject of a legal challenge brought by Earthjustice and awaiting a decision in the Second Circuit district court, which alleges that it fails to assure consumer safety as the FDA’s statute requires because it illegally delegates safety decisions to private companies without any FDA oversight.²³

In addressing CBD, the FDA for the first time acted to preemptively close this loophole when it announced last November: “FDA is also indicating today that it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food.”²⁴

The significance of the FDA’s decision to close the GRAS loophole for CBD goes beyond food, because dietary supplement manufacturers also use the GRAS loophole to evade safety review of new dietary ingredients. By exploiting an exemption that applies to “food ingredients,” dietary supplement manufacturers can avoid the FDA’s “new dietary ingredient” (NDI) safety review for supplements. An estimated 75-80 percent of new ingredients in supplements evade FDA safety review in just this way, according to the industry’s own admission at an FDA Public Meeting two years ago.²⁵

This broken system has multiple overlapping points of failure and will not assure the safety of CBD products. Forcing the FDA to create a pathway that could lead to approval of CBD would mean, practically speaking, that there would be *no assurance of a review for safety for most products*.

Rather than Over-Riding the FDA's Ongoing Process on CBD specifically, Congress Should Direct the FDA to Focus on Concrete Improvements that Address Long-Standing Gaps in Oversight of Food Additives and Supplements

As explained above, a more developed agency evaluation is underway at the FDA, although the timing for public release is being impacted by the need to divert resources to the novel coronavirus pandemic. In addition to the public hearing the FDA held in May 2019,²⁶ the FDA process is required by law to provide ample opportunity for submission of relevant safety and quality control information by CBD proponents.

Consistent with its statutory requirements, for food uses, the FDA can and should request submission of scientific evidence that CBD is safe for particular uses in food, and at particular potencies, and take steps to monitor adverse effects, quality control and contamination concerns. This would incentivize serious study by the food industry of the risks and safe use of CBD products, and would require better quality controls in the supply chain. Such a process might identify doses and/or particular conditions of sale for CBD that would be legal to market.

In addition, Congress should require the agency to update the scientific standards it applies more generally in evaluating the safety of additives. The FDA's so-called "Redbook" and related agency guidance outline the scientific principles and procedures used by the FDA to determine whether new food additives are toxic or unsafe before granting premarket approval.²⁷ Although the FDA states that the Redbook represents its "current thinking on this topic,"²⁸ the latest version of this guidance is 13 years old, and some sections, including those on reproduction and developmental toxicity, are nearly 20 years old. These core scientific standards are in dire need of revision.

In 2014, the FDA recognized the need for another round of updates to the Redbook and it held a public meeting and gathered comments.²⁹ Yet, to date, the FDA has made no progress in updating the agency's core scientific principles and standards for evaluating the safety of substances in food, meaning that these processes continue to be based on outdated and/or inaccurate scientific thinking.

Since the Redbook's last major update 13 years ago, food science and technology has drastically changed, and many newly developed substances have been added to our food. Many of these additives may present unknown health risks to the public, particularly for sensitive subpopulations such as children and pregnant people. Innovative foods are entering the food supply, and FDA's current reviews are insufficient to ensure that they are safe or to ensure consumer confidence in novel foods, slowing their acceptance in the marketplace.

For foods, it is therefore critical that Congress requires the agency to update the scientific standards that the FDA applies as they do not adequately model exposure or account for vulnerable populations. In addition, Congress should close the secret GRAS loophole for substances in food, which would simply require food manufacturers to submit safety data for new ingredients in food for FDA review, as many do already under FDA's current "notification" regime.

Congress Should Provide Critical New Authorities for the FDA Needed to Ensure the Safety of Supplements

For supplements, the safety standard and review process for “new dietary ingredients” (NDIs) is deeply flawed. A manufacturer is expected only to demonstrate to the FDA that an ingredient will “reasonably be expected to be safe under the conditions of use.”³⁰ This is a low bar. Conversely, the FDA must meet a much higher bar to condemn a dietary supplement as adulterated. The Agency must show that the supplement presents a “significant or unreasonable risk of illness or injury” under recommended, suggested, or ordinary conditions of use.³¹ In practice, this has meant that only a single substance—Ephedra—has ever been barred from use in supplements, but only after it was linked to more than 10,000 adverse events, including many deaths.³²

Problematically, many supplement makers have taken the position that a single NDI for a substance is a license for everyone to use it, which for CBD would mean that a single application could open the floodgates for every company. Moreover, whether the FDA’s authority allows the agency to treat synthetic ingredients as distinct from those that are naturally derived remains uncertain.³³ This distinction is important, as synthetic CBD has been associated with different safety issues.³⁴ Due to the lack of a requirement that supplements be listed in a federal product inventory, the FDA also lacks any overall mechanism for monitoring the supplement marketplace for products that are spiked with illegal drugs or are dangerous for consumers.

To compound these serious deficiencies, the FDA’s supplement office has scant resources for enforcement matters, and because supplement products do not have to be listed with the FDA, there is widespread non-compliance with the law. And when regulators are able to inspect facilities, problems are common. In 2019, just over half of the 598 supplement makers inspected for good manufacturing practices were cited by the FDA, most often for what the agency characterized as “basic” failures to follow standards in manufacturing.³⁵ Because ODSP is ill-equipped to deal with the safety and quality issues that CBD supplements may present, the supplement marketplace is a “Wild West.”

Congress should provide additional authority for the FDA to regulate supplements, including those with CBD, by:

- 1) Requiring mandatory product listing and registration of all products sold with the FDA in a public database;
- 2) Strengthening the safety standards and recall authority that the FDA has regarding dangerous supplements;
- 3) Providing FDA authority to recall supplements tainted with drugs (which the agency currently lacks despite the fact that hundreds of supplements have been proven by the FDA’s own tests to be spiked with amphetamines and other illegal and legal drugs);³⁶
- 4) Providing for shared enforcement by allowing enforcement of some elements of federal law in this area by state Attorneys General and citizen suits;
- 5) Creating a premarket approval and spot audit program for specifically identified categories of supplements that are designated to be “high risk” by the agency

(such as: those frequently shown in tests to be tainted with drugs (*e.g.*, sexual enhancement, weight loss, exercise supplements, and those including cannabinoids); and those marketed for use by vulnerable populations, such as pregnant people and children);

- 6) Providing new authorities and funding for specific quality control requirements for products containing cannabinoids or other higher-risk ingredients, including asking the FDA to work with private certification and testing bodies to extend its reach;
- 7) Authorizing the FDA to require warnings and other measures that discourage use of cannabinoids by children and other vulnerable groups for foods, cosmetics and dietary supplements; and
- 8) Creating specific prohibitions on products containing levels of cannabinoids that are above safe use levels as determined by the FDA.

In addition, Congress should require directed rulemakings with deadlines that include:

- 1) Completion, within two years, of the rulemaking and guidance related to new dietary ingredients (NDI), including a clear definition of pre-1994 ingredients and the evidentiary basis manufacturers must have to secure that status;
- 2) Requiring the FDA to revise its 2016 supplement guidance to specify that self-determined GRAS ingredients are ineligible and create a timeline by which companies that previously had self-determined (“secret”) GRAS status must submit an NDI;
- 3) Requiring warning labels on supplements that interact with common categories of prescription drugs with information for consumers on such interactions;
- 4) Requiring a 1-800 number on supplement labels for direct reporting to the agency of adverse events experienced by consumers;
- 5) Creating a post-market testing program to monitor the quality of “high-risk” categories of supplements known to be commonly adulterated, including CBD;
- 6) Requiring mandatory adverse event reporting by companies for all (and not only “serious”) adverse events;
- 7) Providing specific authority to recall, seize, and levy penalties on products with synthetic adulterants, contaminants, mislabeling, and/or more than a trace amount of THC or other synthetic or natural psycho-active cannabis derivatives.

In addition, the agency needs much more robust general funding for inspections and good manufacturing practices development and oversight, and Congress should also provide dedicated funding for the FDA to take action against CBD products that pose the greatest public health risks. High-risk products warranting swift enforcement action include:

- 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 contained 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.

Congress should give the FDA the support it needs to do its job, and fix the many serious shortcomings in its existing authorities. These shortcomings pose a safety risk to consumers of CBD and other products that cannot be ignored. We urge Congress not to erode—but instead to strengthen—the position of the FDA to address these issues in foods and supplements and protect health, as its mission requires.

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

Sincerely,

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Notes

¹ E.g., 84 Fed. Reg. 12969 (April 3, 2019).

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<https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details>. Accessed June 9, 2020.

³ Iffland K, Grotenhermen F. An Update on Safety and Side Effects of Cannabidiol: A Review of Clinical Data and Relevant Animal Studies. *Cannabis Cannabinoid Res.* 2017;2(1):139-154.

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⁶ Pure Relief. *CBD Gummies*. <https://www.purerelief.com/cbd-gummies/>. Accessed June 10, 2020.

⁷ U.S. Food and Drug Administration. “What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding: *FDA strongly advises against the use of cannabidiol (CBD), tetrahydrocannabinol (THC), and marijuana in any form during pregnancy or while breastfeeding.*”

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¹³ Rianprakaisang T, et al. Commercial Cannabidiol Contaminated with the Synthetic Cannabinoid AB-FUBINACA Given to a Pediatric Patient. *Clin Toxicol.* 2019.

¹⁴ Poklis JL, Mulder HA, Peace RP. The unexpected identification of the cannabimimetic, 5F-ADB, and dextromethorphan in commercially available cannabidiol e-liquids. *Forensic Science International.* Volume 294, January 2019, Pages e25-e27. <https://doi.org/10.1016/j.forsciint.2018.10.019>. Accessed June 17, 2020.

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