



## Council for Responsible Nutrition

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### CITIZEN PETITION

June 16, 2020

#### ***Via Electronic Submission***

Division of Dockets Management  
U.S. Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Rm 1061  
Rockville, Maryland 20852

**Re: Citizen Petition Requesting FDA Establish a Regulatory Pathway to Legally Market Dietary Supplements Containing Hemp-Derived Cannabidiol (CBD)**

Dear Sir or Madam:

The Council for Responsible Nutrition (CRN),<sup>1</sup> submits this Citizen Petition pursuant to 21 C.F.R. § 10.30 requesting that the Food and Drug Administration (“FDA” or “the Agency”): (1) exercise its statutory authority to establish a regulation under which hemp-derived cannabidiol (CBD) may be legally marketed as a dietary ingredient; (2) clarify when a hemp-derived substance is subject to the preclusion provisions of 21 U.S.C. § 321(ff)(3)(B); and (3) enforce existing dietary supplement regulations with respect to CBD-containing products being marketed as dietary supplements.

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<sup>1</sup> The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and 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 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, 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 and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN’s Code of Ethics. Learn more about us at [www.crnusa.org](http://www.crnusa.org).

Over a year ago, Congress took a bold step towards ensuring consumers have access to the growing cannabis market and this substance's promising health benefits by removing hemp (as defined in 7 U.S.C. § 1639o(1)) from the Federal Controlled Substances Act. The new statutory definition of hemp removed the controlled substance prohibition against a wide-variety of hemp-derived constituents, including CBD, provided they do not have a delta-9 tetrahydrocannabinol (THC) concentration of more than 0.3 percent on a dry weight basis.

To protect the public health, Congress preserved FDA's authority over hemp-derived ingredients when used in products already regulated by the Agency, such as food, dietary supplements, drugs, and cosmetics. Congress, however, fully intended its actions would allow hemp and its non-THC constituents and derivatives, like CBD, to be available to consumers in a wide-variety of products, including dietary supplements. Congress preserved FDA's authority to ensure that hemp ingredients would be regulated like any other FDA-regulated product under the expansive and comprehensive safety, labeling, manufacturing, and similar requirements already in place. FDA has stalled, however, in allowing CBD's use in dietary supplements, citing a statutory provision of the Food, Drug, and Cosmetic Act (FDCA) intended to protect drug research and development. While incentivizing drug research is a critical part of public health, Congress also gave FDA authority to allow dietary supplements and drug ingredients to coexist by providing FDA the discretion to create regulations allowing a substance to be a legal dietary ingredient despite its use first as a drug. This would ensure drug manufacturers would not have an absolute monopoly on the market for ingredients with a range of both drug and non-drug uses.

Congress and industry have repeatedly requested that FDA use this authority to allow CBD to be a legal ingredient in dietary supplements, consistent with the intent of Congress in legalizing hemp. If ever there was an appropriate time for FDA to use this authority, the time is now. The drug preclusion provision of the FDCA is a "race-to-market" provision designed to help protect drug development, if a drug is approved (or substantially investigated) before a substance is marketed as a dietary ingredient. Here, dietary supplement companies could not even enter the race until December 2018 when Congress removed hemp from the Federal Controlled Substances Act – well after CBD was being studied and approved as a drug ingredient.

FDA has represented that it has been actively exploring the use of this statutory authority to legalize CBD as a dietary supplement ingredient. One year ago, on May 31, 2019, FDA held a widely attended public meeting with the goal of better understanding hemp-derived substances, such as CBD, and how they should be regulated. Over a year after that meeting, FDA has taken no steps to create a legal pathway for CBD use in dietary supplements, other than making vague statements that the Agency is "actively evaluating potential rulemaking to allow CBD in dietary supplements."<sup>2</sup>

CRN shares the Agency's goals that products available to the public should be safe, manufactured in a manner that ensures product quality, and marketed without the use of unauthorized disease

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<sup>2</sup> Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations, Cannabidiol (CBD), Mar. 5, 2020, available at, <https://hempsupporter.com/assets/uploads/FDA-CBD-Report.pdf>.

claims. Such goals can easily be accomplished for CBD products, as CRN has advocated for over a year, by FDA exercising its authority to allow CBD use in dietary supplements and imposing the existing dietary supplement regulatory framework over these products. This structure already provides regulatory requirements for product safety, quality, and claims. The action we request in this Petition will help ensure public safety and spur innovation and economic development for this already burgeoning industry.

#### **A. Action Requested**

1. Exercise FDA's statutory authority and discretion under 21 U.S.C. § 321(ff)(3)(B) (Section 201(ff)(3)(B) of the FDCA) to issue a regulation finding that hemp-derived CBD is a lawful dietary ingredient.
2. Provide guidance clarifying when a substance is considered "an article" as that term is used in 21 U.S.C. § 321(ff)(3)(B).
3. Enforce existing dietary supplement regulations already promulgated in the FDCA and Title 21 of the Code of Federal Regulations (CFR) with respect to hemp-derived CBD products being marketed as dietary supplements.

#### **B. Statement of Grounds**

##### **1. FDA's Position on CBD as a Dietary Supplement Makes Rulemaking Necessary**

FDA takes the position that CBD cannot be used in dietary supplements because of a provision in the FDCA that precludes a substance from being used in supplements if that substance was an "article" that (1) was "authorized for investigation as a new drug . . . for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public;" and (2) "which was not before such . . . authorization marketed as a dietary supplement."<sup>3</sup>

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<sup>3</sup> 21 U.S.C. § 321(ff)(3)(B). FDA's position does not distinguish between different forms of CBD, such as naturally-occurring levels of CBD found as one component of a hemp extract product versus CBD isolates (*e.g.*, the form of CBD found in the prescription drug Epidiolex). FDA Guidance, FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers (last updated April 2, 2019), *available at*, <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers#dietarysupplements>. For purposes of this Citizen Petition, CRN is asking FDA to develop regulations that cover all forms of CBD. CRN, however, is also asking that the Agency provide guidance identifying with specificity what is the "article" for purposes of section 321(ff)(3)(B). See Section B.4. IF FDA does provide guidance, a regulation pursuant to section 321(ff)(3)(b) would only be needed for forms of CBD that are considered the "article."

Specifically, under the FDCA definition of dietary supplement, 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]** . . .*

21 U.S.C. § 321(ff)(3)(B) (emphasis added).

Congress enacted these provisions to protect commercial interests necessary to incentivize drug development—not because of any safety concerns about the use of an ingredient in both dietary supplements and drugs.<sup>4</sup> FDA takes the position that hemp-derived CBD cannot be a dietary supplement because the agency determined that CBD was the subject of substantial clinical investigations as a drug (Epidiolex) that were made public prior to CBD's use in supplements.<sup>5</sup>

## 2. FDA Has Explicit Authority to Regulate CBD as a Dietary Supplement; Using Such Authority Would Fulfill the Intent of Congress

As noted in the text of 21 U.S.C. § 321(ff)(3)(B) above, FDA already has explicit authority to promulgate a regulation finding that dietary supplements containing CBD may be lawfully marketed under the FDCA, despite its use first as a drug. Under this path, FDA would, by regulation, remove CBD from the exception to the statutory definition of a dietary supplement that applies to certain articles that were first approved or investigated as a new drug.<sup>6</sup>

By not acting to create a regulatory framework for CBD in dietary supplements, FDA is, in effect, creating a sweeping monopoly over CBD for drug use. This is not what Congress intended, in general, and particularly in this circumstance. Members of Congress have emphasized to FDA, on

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<sup>4</sup> See, e.g., S. Rep. 103-410, Part V, § 3 (1994); 140 Cong. Rec. S11,709 (daily ed. Aug. 13, 1994).

<sup>5</sup> FDA Guidance, FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answer, last updated April 2, 2019, available at, <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>.

<sup>6</sup> This Petition does not address the legal status of other hemp constituents, such as other cannabinoids and terpenes, as FDA has not indicated that these ingredients are precluded under the drug exclusion provisions. CRN is concerned, however, that FDA's continued inaction on CBD could put these ingredients in jeopardy as supplement companies grapple with how CBD's legal status affects the use of other constituents. A regulation for CBD now would lay out the structure for creating regulations for other cannabinoids and hemp-derived substances, should they be needed, in the future.

multiple occasions, that its “intent was clear with the passage of the Farm Bill that [CBD products] should be legal, and our farmers, producers, and manufacturers need clarity as well as a workable pathway forward regarding the agency’s enforcement and potential regulatory plans for certain CBD products.”<sup>7</sup> FDA can fulfill Congress’s intent and provide this clarity through the rulemaking authority already granted to the Agency. CRN asks that FDA exercise this authority expeditiously and is concerned that further delay on FDA’s part continues to harm both consumers and the industry.

### 3. Issuing a Regulation Would be Consistent with the Agency’s Public Health Mission

#### *a. FDA’s Obligations Under Section 321(ff)(3)(B) Do Not Include a Preliminary Safety Evaluation of CBD*

Over the last year, FDA has indicated that the agency believes it is prevented from moving forward with a regulation until it receives adequate evidence for FDA to determine that CBD is safe for supplement use. This is an odd assertion because section 321(ff)(3)(B) makes no reference to a scientific evaluation of the “article” in the Agency’s decision whether to enact a regulation. Indeed, the statutory provision makes no mention of establishing a safe level for the “article”, which underscores the fact that the provision was inserted into the Dietary Supplement Health and Education Act (DSHEA) to balance the economic interests of pharmaceutical manufacturers with the dietary supplement market.

Had Congress been motivated by safety worries about the use of the article in a dietary supplement, it would not have authorized FDA to make exceptions by determining the article is “lawful.” Rather Congress relied that FDA would be able to invoke the safety standards for dietary supplements otherwise in DSHEA<sup>8</sup> with respect to specific individual products *after* the initial balancing of economic interests had occurred under section 321(ff)(3)(B). While the provision certainly places FDA in a decision-making posture it is less familiar with (*i.e.*, balancing the economic interests of consumers and manufacturers), it calls on the agency to evaluate the effects of handing drug manufacturers a monopoly over an ingredient that has broad dietary supplement indications as well.

CRN continues to insist that a safe level of CBD does not need to be predetermined before the rulemaking process can commence, as the regulatory framework already exists to ensure the safety of a dietary supplement through other statutory provisions and regulations after the

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<sup>7</sup> Press Release from Senator Mitch McConnell, Leader McConnell Discusses Hemp, CBD with Acting FDA Commissioner, June 27, 2019, *available at*, <https://www.mcconnell.senate.gov/public/index.cfm/pressreleases?!D=0B71B14E-5F77-4283-9084-561F67EFBC70>; *see also* Letter from Senator Ron Wyden to the Honorable Alex Azar, Secretary, Department of Health & Human Services and the Honorable Ned Sharpless, Commissioner, U.S. Food and Drug Administration, June 25, 2019 (noting that “[t]he passage of the 2018 Farm Bill is Congress’s clear intent to further advance and support the domestic production and sale of hemp and hemp derivatives like CBD”).

<sup>8</sup> *See* 21 U.S.C. § 331(v) and 21 U.S.C. § 342(f).

rulemaking addressing the definitional objection is completed.<sup>9</sup> Under the rubric of dietary supplement regulations, safety is intended to be addressed on a product-specific basis in the framework already carefully laid out by Congress and FDA. This framework permits FDA to address safety in the context of each unique delivery form, ingredient matrix (*e.g.*, CBD isolate versus hemp extract), dosage, labeling and directions for use, and other unique considerations for each product. FDA has long taken the view that any ingredient not in the market prior to 1994 (as would be the case with all hemp-derived CBD-containing products), are subject to the new dietary ingredient provisions of 21 U.S.C. § 350b, and that each unique manufacturer of such CBD-containing ingredient would be required to file its own new dietary ingredient notification.

*b. Scientific Data Demonstrate CBD's Safety*

Nonetheless, FDA continues to use safety questions as a roadblock to rulemaking and appears to be moving the goalposts for what safety questions must be addressed. At CRN's Annual Conference in October 2019, FDA's Principal Associate Commissioner for Policy, Lowell Schiller, noted that "[i]f we don't think we'll have the data to say that **some level** of CBD can be safely added to a food or dietary supplement, then we wouldn't want to create an exception for CBD."<sup>10</sup> These remarks, along with statements that FDA staff have made in other meetings, all indicate that FDA is seeking assurances that at least some products that companies are seeking to distribute or already distributing would be able to meet FDA's current dietary supplement safety standards. CRN understands that FDA is concerned about using its limited resources in vain by creating a situation where, despite a rulemaking finding that CBD meets the legal definition of a dietary supplement, companies still would not be able to sell CBD products because they could not demonstrate safety.

Over the last year, however, it has become clear that safety data do exist that at least "**some level**" of CBD is safe. In fact, these data have been used to determine safe CBD levels by authoritative foreign regulatory bodies that apply similarly stringent safety standards as the U.S. CRN questions why these well-respected government bodies are able to come to safety conclusions that allow consumers access to safe, beneficial health products up to specific daily levels, but FDA has not been able to determine that a dietary supplement containing any level of CBD could be reasonably expected to be safe.

For example, in February of this year, the UK Food Standards Agency (FSA) issued a statement setting a deadline of March 31, 2021, for industry to submit novel food applications for CBD

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<sup>9</sup> Dietary supplement manufacturers are required to possess a reasonable basis on which they rely to conclude a dietary supplement is reasonably expected to be safe based on the supplement's conditions of use. See 21 U.S.C. § 350b; 21 C.F.R. § 190.6.

<sup>10</sup> Remarks by Lowell Schiller, FDA, Principal Associate Commissioner for Policy – Office of Policy, at the Council for Responsible Nutrition Annual Conference, Nov. 11, 2019, available at, <https://www.fda.gov/news-events/speeches-fda-officials/remarks-lowell-schiller-jd-council-responsible-nutrition-conference-1172019-11072019>.



products, and recommending an upper limit of 70 mg per day for non-drug use of CBD.<sup>11</sup> CRN has publicly urged FDA to follow the lead of the UK FSA and to exercise the statutory discretion provided to it in the FDCA to recognize CBD as a lawful ingredient for use in dietary supplements. Additionally, the Australian Therapeutic Goods Administration (TGA) released a safety assessment for CBD in April of this year, with the overall conclusion that “cannabidiol presents a good safety and tolerability profile at the low dose range of under 60mg/day.”<sup>12</sup>

Last fall, following FDA’s general call for additional safety data, CRN also commissioned its own assessment of the publically available literature to add to the growing body of evidence demonstrating a safe level of CBD. This assessment, which was based on a conservative view of the literature then available, proposed that 40 mg per day was a safe level.<sup>13</sup> In addition to this data, a number of other companies have recently published scientific studies and analysis further contributing evidence that can be used to determine that a safe level of CBD exists.<sup>14</sup> All these determinations bolster the opinions of scientific experts who have recognized that data do exist to determine that hemp extracts containing CBD can be Generally Recognized as Safe (GRAS).<sup>15</sup>

Industry has adequately responded to the FDA’s call for data and expects that CBD be treated like any other dietary ingredient. Even if section 321(ff)(3)(B) did require a safety evaluation to avoid creating a null set of permissible products, the establishment of daily safe levels of CBD by two internationally recognized regulatory bodies and the growing body of publicly available research all collectively provide an affirmative answer to FDA’s long-standing question of

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<sup>11</sup> UK Food Standards Agency, “Food Standards Agency sets deadline for CBD industry and provides safety advice to consumers”, Feb. 13, 2020, *available at*, <https://www.food.gov.uk/news-alerts/news/food-standards-agency-sets-deadline-for-the-cbd-industry-and-provides-safety-advice-to-consumers>.

<sup>12</sup> Australian Government, Department of Health, Therapeutic Goods Administration, “Safety of low dose cannabidiol Version 1.0”, April 2020, *available at*, <https://www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf>.

<sup>13</sup> CRN will be submitting this safety assessment to the FDA’s cannabis docket, Docket No. FDA-2019-N-1482.

<sup>14</sup> See e.g., Chesney et al., Adverse effects of cannabidiol: a systematic review and meta-analysis of randomized clinical trials, *Neuropsychopharmacology*, published online April 8, 2020 (finding that “the available data from clinical trials suggest that CBD is well tolerated and has relatively few serious adverse effects . . .”); Dziwenka, et al., Safety Assessment of a Hemp Extract Using Genotoxicity and Oral Repeat-Dose Toxicity Studies in Sprague-Dawley Rats, *Toxicology Reports* 7 (2020) 376-385; Lopez et al., Effects of Hemp Extract on Markers of Wellness, Stress Resilience, Recovery and Clinical Biomarkers of Safety in Overweight, but Otherwise Healthy Subjects, *Journal of Dietary Supplements*, published online May 27, 2020; and Schmitz et al., Post Marketing Safety of Plus CBD Products, a Full Spectrum Hemp Extract: A 2-Year Experience, *Journal of Dietary Supplements*, published online May 25, 2020.

<sup>15</sup> See e.g., Charlotte’s Web Achieves Self Affirmed GRAS Status, Mar. 17, 2020, *available at*, <https://www.prnewswire.com/news-releases/charlottes-web-achieves-self-affirmed-gras-status-301025721.html>; CV Sciences Achieves Industry’s First Hemp Extract GRAS Self-Affirmation, Sept. 10, 2018, *available at*, <https://ir.cvsciences.com/press-releases/detail/85/cv-sciences-inc-achieves-industrys-first-hemp-extract>; Manitoba Harvest Announces Broad Spectrum Hemp Extract Self-Affirmed Gras Status, May 19, 2019, *available at*, [https://www.prnewswire.com/news-releases/manitoba-harvest-announces-broad-spectrum-hemp-extract-self-affirmed-gras-status-300858631.html#:~:text=MINNEAPOLIS%2C%20May%2031%2C%202019%20%2F,Recognized%20as%20Safe%20\(GRAS\)](https://www.prnewswire.com/news-releases/manitoba-harvest-announces-broad-spectrum-hemp-extract-self-affirmed-gras-status-300858631.html#:~:text=MINNEAPOLIS%2C%20May%2031%2C%202019%20%2F,Recognized%20as%20Safe%20(GRAS)).

whether there are data to support a viable, safe CBD product when evaluated using appropriate dietary supplement safety standards.

*c. Continued Failure to Act Harms Public Health*

FDA's inaction, currently, and in the future if the agency declines to promulgate a regulation, creates a public health concern in its own right. Over 20 million Americans already take CBD dietary supplements,<sup>16</sup> and 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. CRN highlighted these concerns in its July 2019 comment to the Agency, and the Agency's own statements demonstrate how continued inaction allows companies that may not understand dietary supplement regulations – or may not care to follow these regulations – to use this opportunity to fill a marketplace void and may be producing questionable and even dangerous products.<sup>17</sup>

Enforcement of dietary supplement regulations in the current marketplace, as CRN requests in this Petition and further discussed in Section 5 of this Petition below, would better protect consumers, but does not address the long-term issues. To protect consumers from actors that will take advantage of marketplace confusion, FDA needs to create a clear legal pathway for CBD as a dietary supplement. Not only would this ensure that CBD is clearly regulated as a dietary supplement by FDA, but it would subject the ingredient to the many checks the consumer marketplace increasingly imposes on dietary supplements (*e.g.*, third-party testing and auditing by retailers, access to third-party quality seals, etc.).

4. Industry Needs Clarity Now and In the Future as to What is Considered an "Article"

While FDA engages in rulemaking, companies need clearer guidance on the scope of the drug preclusion provisions. This guidance is needed, not only for CBD, but to guide manufacturers moving forward with other cannabinoids and hemp-derived ingredients that also may be of interest to drug manufacturers. Since the dietary supplement definition was enacted in 1994, FDA has provided almost no clarity on when a substance would be the same "article" as a drug.

With regard to CBD, FDA's statements about what specifically is the "article" that is subject to the drug preclusion provisions of 21 U.S.C. § 321(ff) have been broad and general, leaving companies with little understanding of whether CBD, in any form or amount, is permissible. This

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<sup>16</sup> 2019 CRN Consumer Survey on Dietary Supplements, more information available here: <https://www.crnusa.org/resources/2019-crn-consumer-survey-dietary-supplements-consumer-intelligence-enhance-business>.

<sup>17</sup> See CRN Comments submitted to FDA's Docket 2109-N-1482, July 16, 2019, *available at*, <https://www.regulations.gov/document?D=FDA-2019-N-1482-4060>; *see also* Comments by L. Schiller, CRN 2019 Annual Conference ("Many of the manufacturers entering this space lack experience with FDA or DSHEA, and we have serious concerns about issues like harmful contaminants such as pesticides, heavy metals, or other drugs like THC. We're also seeing some egregiously irresponsible behavior, like marketing CBD products for use by infants, or promoting them to treat serious conditions like cancer or opioid use disorder.").



includes whether broad spectrum hemp extracts that contain CBD among other constituents are also a precluded “article” along with CBD isolate.<sup>18</sup> CRN believes that, at a minimum, hemp extracts cannot be classified as the same “article” that is subject to the drug preclusion provisions of the FDCA, simply because those extracts contain CBD. FDA has addressed this issue in other situations, such as where the agency has noted that naturally occurring amounts of lovastatin found in red yeast rice are not the same “article” as when that substance is used in a drug product approved for lowering cholesterol levels.<sup>19</sup>

FDA should take into consideration the following in determining whether CBD in various forms is the same “article” as Epidiolex:

- Hemp extract with CBD is a very different substance from CBD isolate found in Epidiolex. The CBD isolate in Epidiolex has been removed from its other plant constituents, which affects the behavior of the substance. Extracts should be considered in their entirety, including the CBD component, because the behavior of the individual components depends on the extract’s complexity and synergistic effects. A hemp extract containing CBD may contain hundreds of other different constituents, including numerous other cannabinoids, flavonoids, terpenes, and other phytochemicals. This is in contrast to a CBD isolate like Epidiolex, which is a 99 percent pure form of CBD.
- Based on the profile of extracts described above and precedent established by FDA in the lovastatin matter, the drug preclusion provisions should not apply, at a minimum, where a finished extract contains CBD, but the extract bears a similar phytochemical profile as that of the plant (except where substances are eliminated for safety reasons).<sup>20</sup>

Developing guidance distinguishing CBD isolate from other forms, would immediately allow companies to market non-isolate forms of CBD products in compliance with all FDA requirements, including by submitting new dietary ingredient notifications. Currently it is unclear if a company were to submit such an NDI notification for a hemp-extract product, whether the notification would be rejected because the agency has not yet considered this definitional issue.

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<sup>18</sup> As noted in n. 3, FDA’s current guidance document on the regulation of cannabis and cannabis-derived products, FDA simply notes “CBD products are excluded from the dietary supplement definition . . . .” See FDA Guidance, FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers (last updated April 2, 2019).

<sup>19</sup> FDA Letter to S. Pape, May 20, 1998 (summarizing FDA’s decision that Cholestin (a product containing lovastatin) was not a dietary supplement because of the FDCA drug preclusion provisions).

<sup>20</sup> This would apply, for example, to hemp-derived extracts, including standardized hemp-derived extracts that do not concentrate CBD content beyond that which normally occurs as a result of a standard extraction process (*e.g.*, water, ethanol, and CO<sub>2</sub> extraction processes). All extraction process concentrate the compounds in percentages higher than found in the plant, but certain process, such as those described in the sentence above, keep the original plant phytochemical profile intact.

#### 5. FDA Enforcement is Necessary to Protect Public Health

Finally, CRN requests that FDA enforce existing dietary supplement regulations against CBD products that are marketed as dietary supplements. If a company holds its products out to consumers as dietary supplements, such as by Statements of Identity; claims made on labeling, marketing, or other material; inclusion of a “Supplement Facts” box on the label; or other actions, that company should be held to all dietary supplement regulatory standards. These include not only the premarket notification requirements under 21 U.S.C § 350b,<sup>21</sup> as discussed earlier, but also would include ensuring that products were manufactured using appropriate good manufacturing practices (GMP), in facilities that are registered with FDA, that companies are following adverse event reporting requirements, and that products are labeled in compliance with FDA regulations.

FDA’s lack of action and enforcement to ensure that CBD products are regulated as dietary supplements has lead states to step into the role that should belong exclusively to FDA. Multiple states have enacted (or are in the process) of enacting laws and regulations that would impose their own requirements and restrictions on CBD supplements that differ from FDCA requirements on supplements in general. These include testing, labeling, and other requirements that are creating an inconsistent patchwork of regulations,<sup>22</sup> which are likely to remain even if FDA eventually creates a federal regulation, making it less likely that a uniform U.S. marketplace for CBD-containing dietary supplements can be created. Consumer confusion will result.

Congress has provided FDA with additional funds for enforcement actions and CRN urges FDA to use these funds to help ensure the existing marketplace is safe for consumers by ensuring products labeled as dietary supplements meet supplement regulatory standards.

#### **C. Environmental Impact Statement**

CRN maintains that the actions requested in this Petition are exempt from the requirement to provide an environmental impact statement pursuant to 21 C.F.R. § 25.30(h).

#### **D. Economic Impact**

Information on the economic impact of this proposal can be provided if requested.

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<sup>21</sup> FDA should recognize that to date it has been impossible for companies to comply with NDI notification requirements because the Agency has rejected those submitted due to the definitional issue, not because of any safety concerns raised by the Agency. Using its enforcement discretion to allow CBD in products otherwise meeting dietary supplement requirements (or issuing guidance distinguishing forms of CBD as CRN also has requested), would allow FDA within a reasonable timeframe to enforce new dietary ingredient provisions of the law.

<sup>22</sup> See, e.g., Texas Proposed Rules, 25 Texas Health & Safety Code §§ 300.100, *et seq.*; and Virginia S.B. 918, signed into law on April 6, 2020 (Acts of the Assembly, Chap. 660, codified at Code of Virginia § 3.2-4121 and §§ 3.2-5145.1 through 3.2-5145.5).

**E. Certification**

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner that are unfavorable to the Petition.

Sincerely,



Steve Mister  
President & CEO



Megan Olsen  
Vice President & Associate General Counsel