February 21, 2022

Dockets Management Branch

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville, MD 20852

CITIZEN PETITION: CANNABIDIOL'S IMPROPER EXCLUSION FROM THE DEFINITION OF A DIETARY SUPPLEMENT UNDER THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT AND SPECIFIC ENFORCEMENT DISCRETION TO REVIEW PREMARKET NOTIFICATION OF CANNABIDIOL

Dear Sir/Madam:

The undersigned, on behalf of the Natural Products Association ("NPA")[1], submits this petition under 21 U.S.C. §321(ff) and 21 C.F.R. §10.30, among other provisions of law, to request that the Commissioner of Food and Drugs either determine: (1) that cannabidiol ("CBD") is not

[1] Founded in 1936, the Natural Products Association ("NPA") is the nation's largest and oldest nonprofit organization dedicated to the natural products industry. Natural products include a wide array of consumer goods that grow in popularity each year. These products include natural and organic foods, dietary supplements, pet foods, health and beauty products, "green" cleaning supplies and more. Generally, natural products are considered those formulated without artificial ingredients and that are minimally processed. NPA advocates for the right of consumers to have access to products that will maintain and improve their health, and for the right of retailers and suppliers to sell these products. NPA represents over 1,400 members, accounting for more than 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. NPA unites a diverse membership, from the small health food stores to large dietary supplement manufacturers.

NPA played a key role in the passage of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325. This important legislation struck a balance between the need for consumers to have access to and information about safe and effective dietary supplements while preserving the government's interest in protecting the public from unsafe products and false and misleading claims. Currently, NPA advocates before Congress, the Food and Drug Administration ("FDA" or "Agency"), the Federal Trade Commission ("FTC"), and other federal and state agencies, legislatures, state attorneys' general and courts.

excluded from the definition of a dietary supplement under 21 U.S.C. §321(ff)(3); or (2) that the Commissioner exercise enforcement discretion in a specific and selective manner to review the safety data of a CBD product consistent with 21 CFR Part 190.6. Alternately, the Agency may recommend to the Secretary of the Department of Health and Human Services ("HHS"), that the Agency promulgate a regulation, after notice and comment, establishing that CBD is lawful under the Food, Drug and Cosmetic Act (the "Act").[2]

I. ACTION REQUESTED

For the following reasons, based on the facts provided herein, NPA respectfully requests that the Commissioner of Food and Drugs either: (1) determine that CBD is not excluded from the definition of a dietary supplement under 21 U.S.C. §321(ff)(3)(B); or (2) that the Commissioner exercise enforcement discretion in a specific and selective manner over CBD products following a safety review of a notification on an individual dietary supplement product submitted consistent with 21 C.F.R. Part 190.6. Or, in the alternative, the Agency may recommend and support to the Secretary of HHS, that in his discretion he issue a regulation, after notice and comment, establishing that CBD is lawful under the Act.

More particularly, NPA requests that the Agency conclude and state that CBD is a lawful dietary ingredient and is not excluded from the definition of a dietary supplement under the relevant definitions of DSHEA. Should FDA conclude that CBD is not lawful and is excluded from the definition of a dietary supplement under DSHEA's definitions, then the Agency should state that it will scientifically review, safety data related to CBD, including any safety data submitted as part of any premarket regulatory submission. To the extent that the Agency's decisions to the foregoing are governed by overly rigorous safety data requirements—akin to those

[2] 21 U.S.C. §301, *et seq.*

applied to drug approvals—the Agency should alter those policies and only require safety data submissions that accord with the proper standards—i.e., a basis for concluding a reasonable expectation of safety—that is applied to safety determinations of dietary supplements and dietary ingredients.

II. STATEMENT OF GROUNDS

A. Background

1. Exclusion from the definition of a dietary supplement under 21 U.S.C. §321(ff)(3)(B).

Section 201(ff)(3)(B) of the Act, prohibits from the definition of a dietary supplement any article:

- that is approved under 21 U.S.C. §355 (section 505 of the Act); or
- authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.

21 U.S.C. §321(ff)(3)(B). There are two exceptions to §201(ff)(3)(B):

- verifiable, contemporaneous evidence documenting that the article or any other compound containing the article as its active moiety was marketed as a dietary supplement or as a food prior to the article's authorization for investigation as a new drug under an Investigational New Drug ("IND"); or
- the Secretary, at the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the Act.

This section of the Act has come to be known in the industry as creating a "race to market" between those interested in investigating an article as a drug and others interested in marketing the

same article in a product labeled as a dietary supplement. This section of the Act purportedly is intended to preserve the financial and public health incentives to both bring dietary ingredients to market and to conduct research on new drugs.[3]

NPA submits this Petition. As discussed further herein, cbdMD, Inc. ("cbdMD") has met with representatives from FDA to discuss portions of the issues presented herein. cbdMD, in addition to NPA, seeks answers and actions as requested in this Petition.

B. Argument

1. FDA should cease its inequitable interpretation and application of 21 U.S.C. §321(ff)(3).

In passing the Act, Congress charged the FDA to "protect the public health" by ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. §393(b)(2)(A). In 1994, the Act was further amended with the Dietary Supplement Health and Education Act.[4] DSHEA established dietary supplements as a new category of food products with unique standards that comprehensively cover safety, labeling, manufacturing and other related topics. DSHEA was introduced to counteract unnecessarily stringent federal intervention into the manufacturing, sale, and labeling of dietary supplements.[5]

a. The definition of "old dietary ingredients" includes ingredients like CBD that were marketed as dietary ingredients prior to passage of DSHEA.

DSHEA established the definition of a dietary supplement under Section 201(ff) of the Act. Under this definition, a dietary supplement must contain at least one dietary ingredient, be swallowed, not be intended to replace a meal, and not contain an ingredient found to be excluded

[3] FDA Response to BioStratum Inc., Docket No. FDA-2005-P-0259 (formerly Docket No. 2005P-0305). Page 14

[4] Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §301 *et seq.* (1998). Pub. L. No. 103-417, §4, 108 Stat. 4325 (1994).

[5] *See, e.g.,* 103 CONG. REC. S17049 (daily ed. Nov. 23, 1993) (statement of Sen. Hatch).

from the definition of a dietary supplement. DSHEA also established the definition of a "new dietary ingredient" ("NDI") under Section 413(d) of the Act to mean a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994. The term "old dietary ingredient" has never been defined in a statute or regulation, but it is commonly defined as an ingredient that was marketed prior to DSHEA and would satisfy the definition of a dietary ingredient under DSHEA.[6] There is no authoritative list of old dietary ingredients that were marketed in dietary supplements prior to October 15, 1994. Prior to DSHEA, there was no need for a responsible distributor to be concerned with the approval date of a drug, biologic, or when a new drug was authorized for investigation. For these reasons, records of dietary supplement sales and products were often not memorialized or cataloged prior to DSHEA. The Congressional Record that accompanied the passage of DSHEA provides insight. For example, the Senate Report published by the Committee on Labor and Human Resources, of which Senator Hatch was the chairman, stated:

> On occasion, a substance that is properly included as a dietary ingredient in a dietary supplement (food) product may also function as an active ingredient in a drug product. There is nothing particularly surprising about this fact.
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> As an example, the dietary substance, L-carnitine may properly be used as an ingredient in a dietary supplement (as FDA itself has acknowledged), although it is also the active ingredient in a drug product that has been approved by FDA for a particular prescription-only usage. Similarly, the substance caffeine is a natural component of food products such as coffee and tea; it is used as an added ingredient in foods, including carbonated beverages, and it has only been approved by FDA as a drug.

It is clear from the language in the Report that both L-carnitine and caffeine were marketed as both dietary ingredients and approved drugs prior to the passage of DSHEA. It is also clear from the Report's language that Congress intended for these ingredients to continue to be marketed as

[6] 21 U.S.C. §321(ff); 21 U.S.C. §350b(d); and 21 U.S.C. §321(ff)(1).

both drugs and dietary ingredients after the effective date of DSHEA, October 15, 1994. It is telling that the report establishes Congress's intention to allow unnecessarily hindered marketing of dietary supplements without any analysis under, or even reference to, the "race to market" paradigm of Section 201(ff)(3) of the Act as amended by DSHEA. This indicates that Congress intended that articles that were marketed as both drugs and dietary ingredients prior to the effective date of DSHEA could continue to be marked as such under Section 201(ff)(3).

b. Hemp-derived products were in the food supply prior to passage of DSHEA and are not excluded by the Act.

FDA's Draft Guidance *Dietary Supplements: New Dietary Ingredient Notifications and Related Issues* published in August 2016 (herein "Draft Guidance") and directs companies intending to demonstrate that their ingredient was marketed prior to October 15, 1994, to provide documentation that specifies the plant part from which the botanical dietary ingredient was derived. For botanical extracts, the documentation should also specify the extract type. The United States Pharmacopeia ("USP") is an independent, nonprofit organization outside of the US government that was founded to bring a national set of standards to the US by compiling quality specifications used to confirm composition, identity, purity and strength of specified material for use in medicines and food products. In 1848, Congress passed the Drug Importation Act, which officially recognized the USP as setting standards for identity, purity and strength for the specified material. The USP first documented the use of hemp-derived products with its entry, "*Extractum Cannabis. Extract of Hemp*" which was listed as being an alcohol-based "extract of the dried tops of Cannabis sativa—variety *Indica*" in 1850.[7] The USP establishes the historical use of cannabis, its extracts, and its components—including CBD. The inclusion of "*Extractum Cannabis. Extract*

[7] https://archive.org/details/b24907030/page/50/mode/2up?q=hemp.

of Hemp" in the 1850 edition of the USP definitively meets the bar established by the Act for a company to demonstrate that an ingredient was marketed in a product prior to the passage of DSHEA because it shows that CBD was marketed as a dietary ingredient nearly 150 years before the passage of DSHEA.[8] The evidence demonstrating CBD's presence in the diet is widely available and irrefutable, so the Agency should easily determine that CBD is not excluded from DSHEA's definition of dietary supplement/ingredient. Accordingly, the Agency could and should conclude that CBD is not excluded by the drug exclusion of Section 201(ff)(3) and state that CBD is a dietary ingredient as defined by DSHEA.

2. cbdMD has presented a dossier of data to the Agency demonstrating the safety of CBD and cbdMD stands ready, willing, and able to submit a full NDI submission should the Agency agree to earnestly review the data.

Although it is unnecessary for the Agency to consider CBD safety data because of CBD's status as an old dietary ingredient, cbdMD studied CBD's safety so that it could further demonstrate the untenability of the Agency's historical treatment of this dietary ingredient and its corresponding safety data. cbdMD spent approximately $1,000,000.00 (USD) to prepare identity and safety data to answer all safety questions posed by the Agency, and the Agency has no proper justification to refuse review of cbdMD's data or NDI submission under the faulty pretense that CBD is excluded from the definition of a dietary supplement under DSHEA, or by dodging the consideration of convincing safety data. Indeed, cbdMD conducted these studies with the well-known understanding that the CBD market has evolved faster than the related regulatory

[8] There are ample records available demonstrating that CBD was marketed as a dietary ingredient prior to CBD's approval as a drug or passage of DSHEA. However, as a general matter, it would be unworkable, inefficient, and unlikely to benefit consumers or public health to require companies to maintain records to demonstrate that such products were on the market prior to the passage of DSHEA. There is no basis in DSHEA or otherwise in the Act to institute such a requirement, and nothing specified herein should be construed to support such a requirement.

framework and seeks to provide safe products to an ever-growing market in a good-faith effort to promote public health. To this end, former Commissioner Hahn on March 5, 2020, stated:[9]

> The marketplace for CBD-containing products is quickly evolving and it is critical that we work together with stakeholders and industry to develop high-quality data to close the knowledge gaps about the science, safety and quality of many of these products, as well as further evaluate any potential benefits outside of the one FDA-approved drug product to treat two rare, severe pediatric epilepsy disorders.
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> To address the questions and concerns we've already raised, we're seeking reliable and high-quality data. This includes data on, among other things: the sedative effects of CBD; the impacts of long-term sustained or cumulative exposure to CBD; transdermal penetration and pharmacokinetics of CBD; the effect of different routes of CBD administration (e.g., oral, topical, inhaled) on its safety profile; the safety of CBD for use in pets and food-producing animals; and the processes by which "full spectrum" and "broad spectrum" hemp extracts are derived, what the content of such extracts is, and how these products may compare to CBD isolate products.
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> Given the importance of answering these questions, we're exploring a number of ways to address the data gaps as quickly as possible. This includes encouraging, facilitating and initiating more research on CBD, providing venues for industry and researchers to share new data with the agency and identifying opportunities to further collaborate with our federal partners at Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration and National Institute on Drug Abuse on this important issue.

cbdMD has compiled a dossier of identity and safety data for submission as a novel food ingredient for the European Union, and for submission in support of a new dietary ingredient notification ("NDIN") to FDA.[10] The United Kingdom has already reviewed this data and the European Union is on track to review it as well. cbdMD has presented this information to FDA as part of its preparations for the NDIN process. Yet cbdMD will be forced to submit its NDIN without the full scope of safety data it has compiled unless the Agency agrees to review the data and provide cbdMD, in the form of an NDIN response letter, with its determination of whether it

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[9] https://www.fda.gov/news-events/press-announcements/fda-advances-work-related-cannabidiol-products-focus-protecting-public-health-providing-market (emphasis added)

[10] Attached hereto as Exhibit A is a redacted copy of the NDI submission that cbdMD has prepared.

agrees or objects to it on its scientific merits and not on a broad policy statement on drug exclusion. After all, submitting cbdMD's confidential data to the Agency without the guarantee that it will be reviewed and appropriately replied to does nothing other than expose cbdMD to the risk of disclosure of the data along with potential misrepresentations of the data without any benefit to cbdMD. cbdMD should not be forced to expose itself to this risk after spending approximately $1,000,000.00 (USD) to study CBD unless it will receive a substantive response from FDA. For this reason, this Petition requests that the Agency confirm that it will actually review and reply to cbdMD's safety data in earnest before it is included with cbdMD's NDIN. Without the pathway for the agency to review the safety data consistent with the statute the agency has effectively reversed the marketplace, providing an advantage to companies who will NEVER conduct the required safety studies, meet cGMP and meet other regulatory requirements.

cbdMD is a reputable member of industry that has taken significant steps to ensure and demonstrate that its products are safe consistent with scientific principles and the statute. cbdMD's ingredients, including the one subject to the proposed NDIN, are produced under good manufacturing practice ("cGMP") conditions from the *Cannabis sativa L.* plant. That ingredient is of natural origin and entirely sourced from domestic farms. cbdMD's CBD was fully characterized, including all chemical constituents, with the use of validated methods established by the Association of Agricultural Chemists ("AOAC") for quantification of sixteen cannabinoids. AOAC's methods and validations are considered reliable and often used to establish standards for these types of analyses.[11] AOAC's methods and protocols were properly applied to cbdMD's studied ingredient and demonstrate that cbdMD can ensure the identity of its ingredient,

[11] *See* https://www.aoac.org/about-aoac-international/.

manufactures its product under the appropriate GMP's, and that cbdMD's natural products are wholesome and safe at the marketed doses.

During cbdMD's testing, five representative batches were screened for contaminants that may be present in hemp-derived products, including microbials, mycotoxins, residual solvents, pesticides, and heavy metals. The ingredient consistently and fully complies with established specifications. Accelerated and real-time stability testing were performed on the ingredient and on final finished product formats containing the ingredient to assess composition across the suggested life of the product. The composition was stable and within specifications for the proposed shelf life. In compiling its safety dossier on the ingredient, cbdMD commissioned a series of toxicological studies, including a 14-day dose-range finding study with pharmacokinetics, a 90-day subchronic study with recovery, and a combination of genotoxicity studies and reprotoxic assessments. The data demonstrates that the ingredient is not genotoxic and is reasonably expected to be safe over subacute and subchronic exposures at the proposed level of consumption to be included in the proposed NDIN.

FDA has already received several NDINs for CBD. These earlier notifications received letters indicating that, due to FDA's position on CBD being excluded from the definition of a dietary supplement, the notifications would not receive a substantive review of the submitted identity or safety data. Two recent notifications received response letters with comments indicating that the evidence presented as the general history of use of the ingredient was too vague and did not provide an adequate description of the cannabis preparations (e.g., composition), serving levels, or frequency and durations of use for comparison relative to the proposed ingredient use in the NDIN. One of the notifications included toxicology data from a subchronic study performed on the ingredient but, according to the agency's response letter, did not provide data to address the

Agency's concerns related to hepatoxicity and reproductive toxicity. cbdMD's safety data contains substantial data that specifically addresses those endpoints and cannot be ignored under FDA's prior rationales. Further, cbdMD has sold millions of products to consumers in the last few years and has never received an adverse event report from a consumer. cbdMD has thus conducted the robust testing that demonstrates that its products are reasonably expected to be safe and should allay any concern for the public health, thereby warranting that the Agency fulsomely review and respond to any data submitted by cbdMD concerning its CBD ingredient.

Clearly, cbdMD has done its due diligence to establish the safety of CBD through its extensive testing. However, that safety data can only benefit the public if it is reviewed and appropriately replied to in earnest by the Agency. And that data can only be reviewed and replied to if the Agency changes course from its present practice of refusing to provide a substantive review and reply of safety data of NDINs concerning CBD—even after the Agency has specifically requested such data. Not only does this refusal deny a regulatory path to market for safe CBD products made by reputable companies, but it also incentivizes bad actors to avoid following the rules because they know that FDA currently has no intention of acknowledging CBD under an NDIN or taking action to remove otherwise unsafe products from the market. The current status of CBD regulation by FDA is antithetical to the Agency's mission to promote public health. Thus, the Agency should state that it will scientifically review, and then substantively reply to the CBD safety data that has been submitted thus far along with the data that cbdMD will submit once the Agency has agreed to review and appropriately reply to it.

3. FDA is improperly applying drug approval requirements to CBD by requiring safety data in a manner not in accord with the Act.

A review of the previously submitted NDINs demonstrates that the safety data requirements imposed by the Agency relative to CBD differ from what has been required for other

supplements and is akin the requirement for drug approval. cbdMD presented safety data for CBD during its pre-NDI meeting to demonstrate CBD's safety—data that was well-received by the Agency's representatives in attendance. But an NDIN need only present threshold evidence showing that the dietary ingredient is reasonably expected to be safe under the supplement's labeled conditions of use under 21 U.S.C. §350b(a)(2). The standard for showing that a new dietary ingredient is reasonably expected to be safe is far less rigorous than the safety standards applied to drug approval submissions. While cbdMD's CBD safety data exceeds the criteria that should be applied to NDINs, it is not at all clear if it will satisfy the Agency's moving-target requirements for demonstrating safety of hemp-derived products. The Agency has been improperly applying drug approval rigor to its safety reviews of CBD as a dietary ingredient, demonstrating its arbitrary and capricious application of the Act. FDA should cease to require safety data submissions that exceed what is required by the Act for articles marketed as dietary ingredients or dietary supplements.

cbdMD is a natural product company. Natural products are used safely every day as both foods and drugs. The conditions of use in cbdMD's submission are not suggesting that a consumer should ingest a drug-level dose of CBD. In fact, the level of CBD in their dietary supplement (at 50 mg/day) is at approximately *10-30 times lower* than the doses for approved CBD drugs.[12] Despite the striking differences in dose, there is a persistent misconception that hemp-derived CBD-containing dietary supplements should be treated like drugs. When statements that "cannabis-containing consumer products have not undergone the type of drug safety and efficacy testing that was performed with Epidiolex or Marinol."[13] are made in public forums, it implies that

[12] https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210365lbl.pdf
[13] https://pubmed.ncbi.nlm.nih.gov/33175977/.

there is a similar standard for safety and efficacy testing applied to dietary supplements and drugs. This is not the case because dietary ingredients and dietary supplements are not subjected to this same rigor as explained by the plain terms of DSHEA. However, CBD and hemp products are being subjected to a different standard than other dietary ingredients or supplements. In fact, supplements containing CBD are being subjected to the standard applied to drugs, which has no basis in the Act, Congressional intent, or formal rulemaking. Nevertheless, despite there being no requirement that cbdMD submit safety and identity data to the same level of rigor as drugs, cbdMD has gone to great lengths to provide data beyond what is required for a NDIN and approaching what is expected for the preclinical study of drug candidates.

As noted above, we are requesting that FDA review cbdMD's safety data and respond substantively in an NDIN respond letter in earnest on its specific scientific merits. However, even if the Agency refuses to do so, it should acknowledge that FDA's overly rigorous safety data requirements for CBD have no basis in the Act. DSHEA was introduced to counteract unnecessarily stringent federal intervention into the manufacturing, sale, and labeling of dietary supplements (i.e. treating dietary ingredients as unapproved food additives or drugs requiring premarket approval), and CBD should not be required to adhere to drug-like stringency based solely on ill-conceived preconceptions about CBD.[14] Indeed, cbdMD does not solely seek a broad policy statement from the agency on CBD's universal qualification as a lawful dietary ingredient not excluded from the definition of a dietary supplement — as the Agency has avoided a broad policy conclusion on CBD due to its stated belief that more universal safety data is needed. But, nothing precludes the Agency from reviewing cbdMD's submission on its merits and replying with a formal decision because the Agency has NOT to date stated it could not review a single

[14] *United States v. Two Plastic Drums of Article of Food*, 791 F. Supp. 751 (C.D. Ill. 1991).

supplement product on its scientific merits consistent with statutory and regulatory authorities that mandate the review of a specific product or ingredient.[15] Therefore, we are asking the Agency to follow the intent of Congress as stipulated in DSHEA, and review, consider, and issue a formal decision concerning cbdMD's safety and identify data utilizing the proper analysis applied to dietary supplements.

C. Conclusion

We ask the Agency to properly conclude that CBD is an old dietary ingredient and, as such, does not fall under the drug exclusion provision of DSHEA. In the alternative, given the awareness of the Agency's reluctance to issue a broad policy statement, we request that the Agency agree to scientifically review, and substantively reply concerning the safety data that cbdMD has compiled in accordance with the Agency's authorities and the regulations for dietary supplement products, suspending their desire to invoke the drug exclusion clause, to conduct an actual review of the science on a case-by-case basis. cbdMD has presented FDA with the information that they continue to say FDA lacks and are asking them to review it in earnest. Despite repeated requests from multiple stakeholders and safety data presented in a number of forums, FDA continues to point to a lack of safety data, which cbdMD has presented. Now, we ask that FDA review the available safety data one notification at a time, the way they would for any other new dietary ingredient.

As former FDA Commissioner Dr. Hahn noted, it would be a "fool's errand" to try to remove CBD from the marketplace, and that the Agency will possibly issue a regulation to create a pathway to market for CBD and possibly other cannabinoids in dietary supplements and conventional foods in the immediate future. It would be in the best interest of all stakeholders that

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15 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=190.6; https://www.fda.gov/food/new-dietary-ingredients-ndi-notification-process/new-dietary-ingredients-dietary-supplements-background-industry.

FDA actively use all tools at their disposal to meet their mandate of protecting and promoting the public health in the interim, such as those provided above. If the Agency is overly concerned about an omnibus policy or regulation on CBD, there is nothing in the Act restricting the agency from reviewing the safety data of an ingredient and/or supplement on a case-by-case, product-by-product basis. In fact, which is the very structure of the Act and the Agency's mandate establishing the requirement to review an NDI or a supplement containing a new ingredient through that specific lens.

NPA respectfully requests that the Commissioner of Food and Drugs either determine, based on the facts provided herein, that CBD is not excluded from the definition of a dietary supplement under 21 U.S.C. §321(ff)(3)(B) and can be submitted for review as an NDI and will NOT receive a response that it is ineligible as a dietary supplement or ingredient under the definition of a dietary supplement. In the alternative, we ask the Agency to recommend and support to the Secretary of HHS, that, in his discretion, he issues a regulation, after notice and comment, finding that CBD would be lawful under the Act.

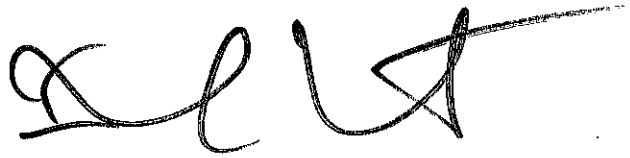
III. ENVIRONMENTAL IMPACT

The Petitioners claim a categorical exclusion from the requirements for an Environmental Assessment under 21 CFR §25.32 in light of the fact that the FDA granting NPA's request will not affect the environment.

IV. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which is unfavorable to the petition. If I received or expect to receive payments, including cash or other forms of consideration, to file

this information or its contents, I received or expect to receive those payments from the following persons or organizations: NONE. I certify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.



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