CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

CITIZEN PETITION

November 14, 2019

Submitted Electronically

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1061, HFA-305
5630 Fishers Lane
Rockville, Maryland 20852

Re: A Citizen Petition Requesting FDA Establish a Regulatory Pathway to Legally Market Dietary Supplements Containing Cannabidiol (CBD) by Issuing a Regulation Finding that the Article, CBD, is Lawful.

Dear Sir or Madam:

The undersigned, Consumer Healthcare Products Association (CHPA), submits this citizen petition to address the definition of a dietary supplement under section 201(ff) of the Federal Food, Drug and Cosmetic Act (FDCA or the Act), 21 U.S.C. § 321(ff). We request that FDA exercise its statutory authority and discretion to engage in rulemaking that establishes a regulatory pathway to legally market dietary supplements containing cannabidiol derived from hemp (as defined in 7 U.S.C. §1639o(1)) (CBD). Specifically, we request that FDA issue "a regulation, after notice and comment, finding that the article [CBD] would be lawful under" the Act. 21 U.S.C. § 321(ff)(3). We also propose that the resulting regulation require that manufacturers of CBD-containing dietary supplements submit new dietary ingredient (NDI) notifications to FDA.

At the same time, we support FDA's continued enforcement of current statutory requirements to market drugs containing CBD, namely through the new drug application (NDA) approval process. We also request that FDA continue and increase enforcement for CBD products that bear inappropriate claims or otherwise fail to comply with applicable law.

CHPA is the 138-year-old national trade association representing manufacturers and distributors of over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. Our mission is to empower the public to exercise self-care by preserving and expanding choice and availability of these consumer healthcare products.

Consistent with our mission, we share the agency's goals to help ensure public safety and product quality. CBD-containing products are flooding the market place, engendering broad consumer demand and intense commercial interest. The action we request in this petition will help FDA by spurring submission of much-needed data under the NDI notification process. The data should help inform FDA as it establishes a broader regulatory framework for CBD products.

A. Action Requested

1. Establish a regulatory pathway to legally market dietary supplements containing CBD derived from hemp by promulgating regulations under 21 U.S.C. § 321(ff)(3)(B), stating that the article, hemp-derived CBD, is lawful under the FDCA. FDA has the authority to act quickly under section 553(b) of the Administrative Procedure Act (APA) to establish this pathway by issuing an interim final rule.

2. Maintain the status quo for medicines containing CBD, meaning continue to enforce the statutory requirements and protections under the NDA process, including with regard to approved indications and established safe dosages.

3. Continue and increase enforcement action against unscrupulous manufacturers making illegal drug claims or otherwise failing to comply with the FDCA with regard to CBD-containing products.

4. Continue to monitor emerging safety issues, if any, concerning CBD-containing products.

B. Statement of Grounds

1. Issue a Regulation Finding the Article, CBD, Lawful Under the Act.

CHPA shares many of FDA's priorities, particularly ensuring public safety and product quality. Informing consumers so that they can make appropriate product choices is also a key role that industry and government share. These priorities apply to hemp-derived and CBD products (which are becoming ubiquitous in the marketplace) in the same manner as other products under FDA's jurisdiction. In other words, FDA needs to act now to catch up to intense consumer demand for and commercial interest in these products, which are currently largely unregulated.

To that end, FDA should exercise its authority under 21 U.S.C. § 321(ff)(3)(B) and promulgate regulations stating that dietary supplements containing CBD derived from hemp (as defined in 7 U.S.C. §1639o(1)) may be lawfully marketed under the FDCA. FDA's authority and discretion to take this path is explicit in the statute and needed to ensure that products are appropriately regulated. Under this path, FDA would, by regulation, take CBD out of the exception to the statutory definition of a dietary supplement that applies to certain articles that were earlier approved (or investigated) as a new drug.

Under the Act, a dietary supplement is defined to, among other things:

> *(A) include an article that is approved as a new drug under section 505 or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful . . .; and*

(B) not include —

(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), 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) (emphasis added).

We ask that FDA act swiftly and exercise this discretion by issuing an interim final rule, finding that the article, CBD, is lawful under the Act. FDA's authority to issue an interim final rule is explicit under APA section 553(b), in that a notice of proposed rulemaking is not required where the Agency finds that there is good cause to waive normal rulemaking requirements.

FDA can issue an interim final rule where it finds that an up-front notice and comment period is impracticable, unnecessary, or contrary to the public interest. For the reasons cited herein, including the intense consumer and commercial interest in CBD-containing products, we believe that FDA would be acting in the public interest if it issued an interim final rule that CBD is lawful under the Act.

In the alternative, if FDA engages in notice and comment rulemaking, we urge that it be accompanied by guidance on enforcement discretion for reputable companies that comply with the terms of any proposed rule as well as all other applicable law.

a. NDI notifications will provide FDA with important data.

As of the date of this petition, we are not aware of evidence that CBD as a dietary ingredient has been present in the food supply or used as an article in food. Therefore, a supplement manufacturer or ingredient supplier would need to provide evidence establishing that CBD as a dietary ingredient will be reasonably expected to be safe as used in its product. In other words, manufacturers would need to file new dietary ingredient (NDI) notifications for CBD. FDA regulations should be explicit in this regard. NDI notifications must contain information that provides the basis on which the manufacturer relies to conclude that the dietary supplement containing the NDI is reasonably expected to be safe, including among other information:

- the level of the NDI in the dietary supplement;
- the conditions of use recommended in the labeling of the supplement; and
- safety evidence establishing that the NDI is reasonably expected to be safe when used under the conditions recommended or suggested in the product's labeling.

21 C.F.R. § 190.6.

Using this approach, we are of the view that FDA would not need to predetermine the precise safe dietary supplement dose for CBD prior to proposing a rule. Instead, the burden of providing safety evidence falls to the party notifying FDA. Entities filing NDI notifications must meet the standard for sufficient

evidence of safety to establish that the CBD-containing dietary supplement will reasonably be expected to be safe. Along these lines and to ensure FDA gets the information it needs, we encourage the Agency to issue specific guidance on the appropriate content and format of NDI notifications for CBD-containing dietary supplements. Specific guidance will increase efficiency of FDA's review of these notifications.

The NDI notification process will provide FDA with much-needed data on CBD, including data submitted by NDI notification filers in response to specific FDA questions or requests for more information. This information may be helpful to FDA as it establishes a framework for regulating CBD products more broadly. In addition, the 75-day wait to enter the market will provide FDA with assurance that it is aware of products produced and distributed by reputable manufacturers.

b. Reputable manufacturers of high-quality products deserve certainty and understanding of the agency's enforcement discretion as they prepare to enter the market.

Recognizing that rulemaking can be a complex and lengthy process, we urge FDA to act promptly. If the Agency goes through the usual process of issuing a proposed rule followed by notice and comment before issuing a final rule, it should at the same time establish, through guidance or other appropriate regulatory mechanism, the conditions under which it will exercise enforcement discretion for responsible manufacturers of CBD-containing dietary supplements. Currently, it appears that FDA is taking enforcement action only against the more egregious violators with regard to CBD products. Yet, FDA has failed to articulate the basis for or scope of this discretion.

We suggest that FDA's enforcement discretion be conditioned on manufacturers and suppliers of CBD-containing dietary supplements taking certain steps to assure product quality, including:

- Sourcing and identifying the article appropriately. That is, sourcing in compliance with the provisions of the 2018 Farm Bill, which legalized the cultivation and sale of hemp and the hemp plant and any of its parts and derivatives (including cannabinoids) that contain no more than 0.3% of the psychoactive compound tetrahydrocannabinol (THC).
- Establishing that the product is reasonably expected to be safe by complying with NDI notification requirements under the FDCA.
- Complying with other relevant statutory and regulatory provisions for dietary supplements, including labeling appropriately, substantiating any claims, and complying with applicable regulations on good manufacturing practices and serious adverse event reporting.

In the absence of an interim final rule, FDA should set out these conditions in guidance or another appropriate published document.

2. Regulating Medicines that Contain CBD.

CHPA supports FDA's continued enforcement of the statutory protections established through the NDA process for medicines that contain CBD. The NDA process provides a premarket approval pathway for sponsors to develop clinical and other required data to bring cannabis-derived drug products to market by demonstrating safety and effectiveness for particular indications, at safely-established dosages, and subject to other FDA-approved labeling.

Importantly, drug indications are off limits – for example for the treatment of certain seizures – and dosages for which safety has been established under an NDA (see EPIDIOLEX® (cannabidiol) oral solution, Full Prescribing Information (Dec. 2018)) should remain subject to the drug approval process and not be considered appropriate for CBD-containing dietary supplements.

The NDA premarket approval process should also be available to manufacturers of nonprescription medicines containing CBD, provided that the sponsor submits sufficient data and other information needed to support the proposed nonprescription use.

3. Ensuring Consumer Safety and Product Quality through Enforcement.

It is clear that FDA is aware of the intense consumer and commercial interest in CBD and hemp-derived products broadly. With little regulatory oversight, the marketplace includes CBD products of varying degrees of quality, an array of unapproved drug claims, and in some cases even fraudulent products. For example, products sold directly to consumers in the marketplace may claim to contain certain levels of CBD, when in fact they contain none or they contain CBD at multiples above that described in the labeling.

By way of example, during FDA's May 31, 2019, public hearing on cannabis or cannabis-derived compounds, Dr. Bill Gurley, University of Arkansas for Medical Sciences, presented the results of a survey of 25 products purporting to containing CBD. Only four contained within 80-120% of the labeled amount. Several products had no to minimal amounts of the labeled level of CBD, and several contained THC. (See *Content vs Label Claim: A Survey of CBD Content in Commercially Available Products*, Gurley, May 31, 2019, presentation at https://www.fda.gov/media/128364/download. Accessed Oct. 21, 2019.)

There are any number of products sold directly to consumers in the marketplace, both for oral and topical use, that bear drug claims despite lacking approval. FDA has sent Warning Letters to firms making particularly egregious claims, but we are not aware of any further enforcement activity against such firms. This situation may leave consumers at risk.

For products that bear egregious and unsupported drug or other claims or otherwise violate the FDCA, we support increased FDA enforcement, including:

- Conducting more facility inspections and issuing Warning Letters accordingly. We were encouraged by at least two recent FDA letters to firms that were the result of facility inspections. (See Sept. 19, 2019, FDA letter to Herbal Healer Academy, Inc. at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/herbal-healer-academy-inc-570957-09122019; and Sept. 18, 2019, letter to Alternative Laboratories at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/alternative-laboratories-586947-09182019. Accessed Oct. 21, 2019.)
- Issuing consumer alerts and playing a greater role in raising public awareness about unsupported claims.
- Increasing scrutiny and other enforcement activities related to imported products.

FDA can step up these important enforcement activities under existing authority, without further legislation or rulemaking.

4. Continuing to Monitor Safety.

This petition's requested action for dietary supplements containing CBD would not interfere with FDA's ability to monitor any safety signals that may emerge. The agency's Center for Food Safety and Applied Nutrition Adverse Event Reporting System captures both spontaneous reports and serious adverse events

that manufacturers of CBD-containing dietary supplements would be required to report under FDCA section 761, 21 U.S.C. § 379aa-1. These reports, if any, may be useful as FDA continues to establish a broader regulatory framework for CBD products.

C. Environmental Impact

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.30(h).

D. Economic Impact Statement

Petitioner will, upon request by the Commissioner, submit economic impact information under 21 C.F.R. § 10.30(b)(3).

E. 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 that are unfavorable to the Petition.

Sincerely,

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