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MEMORANDUM

From: Martin J. Hahn
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Re: **Council for Responsible Nutrition Submits Citizen Petition Requesting FDA Rulemaking to Allow CBD and other Hemp-Derived Ingredients in Dietary Supplements**

The Council for Responsible Nutrition (CRN) submitted a citizen petition 1/ to the Food and Drug Administration (FDA) requesting that FDA:

1. FDA 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 USC 321(ff)(3)(B); and
3. Enforce existing dietary supplement regulations with respect to CBD-containing products being marketed as dietary supplements.

This memorandum provides background on the legal provisions FDA views as preventing the lawful marketing of CBD as a dietary supplement and food – known as the "exclusionary clauses" of the Federal Food, Drug, and Cosmetic Act (FFDCA) as well as a summary of CRN's citizen petition and how the requested actions would alter the regulatory scheme for CBD products. 2/

Background on the Exclusionary Clauses of the Federal Food, Drug, and Cosmetic Act

Two similar provisions in the FFDCA have been interpreted by FDA to prohibit the marketing of hemp-derived CBD as a food or dietary supplement ingredient, known as the "exclusionary clauses" of the FFDCA. The exclusionary clause for dietary supplements is found within the definition of dietary supplements in the FFDCA, Section 321(ff)(3)(B); the exclusionary clause for foods is found in the prohibited acts section of the FFDCA, Section 301(ll). Importantly, CRN's petition only addresses the exclusionary clause applicable to dietary supplements, and does not request any FDA action pertaining to the exclusionary clause for foods or otherwise address a lawful pathway to the use of CBD in foods.

1/ *See* FDA Docket FDA-2020-P-1582-0001, Citizen Petition from the Council for Responsible Nutrition.

2/ This memorandum is offered for general information and educational purposes. It is not offered as, intended as, and does not constitute legal advice. It is not intended to create, and receipt of it does not constitute, a lawyer-client relationship.

The exclusionary clause for dietary supplements provides that the definition of "dietary supplement" does not include "an article" that was either approved as a new drug, antibiotic, or biologic, or subject to substantial clinical investigations as a drug, antibiotic, or biologic which have been made public, unless the article was first marketed as a food or dietary supplement prior to the FDA approval, certification, licensing or authorization, or the Secretary issues a regulation finding the article would be lawful for use as a food or dietary supplement. FDA has consistently taken the view that this provision applies to hemp-derived CBD due to substantial clinical investigations of CBD as a drug, including FDA's approval of Epidiolex® in June 2018.

The statute provides two pathways to overcome the exclusionary clause when there have been substantial clinical investigations of an article that has been authorized for use under an IND. First, the exclusionary clause does not apply if companies can demonstrate they marketed the article as a dietary supplement or food prior to the authorization of the IND. Second, FDA can issue a regulation authorizing the lawful marketing of the article as a food or dietary supplement. The CRN citizen petition addresses both of these provisions by first asking FDA to engage in rulemaking that would authorize the marketing of hemp-derived CBD as a dietary supplement. The citizen petition also asked FDA to provide clarity on the definition of article for purposes of the exclusionary clause. For example, CRN asserts hemp extracts that contain CBD should not be classified as the same article when the drug studied under the IND and approved by FDA involved a 99 percent pure CBD while many commercially available hemp extract contain numerous cannabinoids other than CBD, flavonoids, terpenes, and other phytochemicals.

CRN's Citizen Petition

CRN argues in its citizen petition that FDA's position on the exclusionary clause as applied to CBD has prevented a lawful pathway to market for CBD dietary supplements and created a de facto monopoly over CBD for drug use. CRN contends that Congress intended for the 2018 Farm Bill to open the marketplace for CBD products, and that FDA should act expeditiously to regulate such products because further delay could harm both consumers and the industry.

CRN requests that FDA engage in rulemaking to allow the use of CBD in dietary supplements. CRN explains that FDA has stated several times that FDA cannot proceed with a regulation until the agency receives adequate evidence for FDA to determine CBD is safe for supplement use. However, CRN notes that the statute does not require any scientific evaluation of the "article" for purposes of the exclusionary clause – and that FDA could continue to ensure the safety of dietary supplements containing CBD through its premarket authority, namely, the filing of New Dietary Ingredient Notifications (NDINs). CRN contends that FDA could pursue rulemaking to allow CBD in dietary supplements and subsequently evaluate the safety and levels of use of specific ingredients through its NDIN review process. CRN also explains that foreign authoritative regulatory bodies have successfully determined safe levels of CBD based on available data, pointing to the UK Food Standards Agency recommending an upper limit of 70 mg CBD per day for non-drug uses, and the Australian Therapeutic Goods Administration safety assessment that CBD presents a good safety and tolerability profile at amounts under 60 mg/day. CRN commissioned its own assessment of the publicly available scientific literature and, based on a conservative view of the literature available, proposed a safe amount of up to 40 mg CBD per day. CRN states it will be submitting this safety assessment to the FDA docket.

CRN asserts that if FDA continues to not provide a lawful pathway for CBD dietary supplements, public health would be harmed. CRN estimates that over 20 million Americans already take CBD

dietary supplements, and the lack of federal regulation and robust oversight of these products could contribute to questionable or dangerous CBD products on the market. To that end, CRN requests that FDA enforce its existing dietary supplement regulations against CBD products marketed as dietary supplement, including not only the premarket NDIN requirements, but also ensuring good manufacturing practices (GMPs), facility registration, following serious adverse event reporting requirements, and labeling and marketing in accordance with FDA's regulations.

CRN also asks FDA to issue guidance on the scope of the exclusionary clause as applied to not only CBD, but other hemp-derived ingredients and cannabinoids as well. CRN believes that at a minimum, FDA should clarify hemp extracts cannot be considered the same "article" subject to the exclusionary clauses simply by virtue of containing CBD, and that FDA should take into consideration the form of the ingredient when determining whether the exclusionary clause applies. Specifically, CRN states that CBD isolate or highly purified form of CBD is inherently distinct from a hemp extract that contains a variety of components of the plant including cannabinoids other than CBD, terpenes, flavonoids, and other phytochemicals. CRN states that FDA should address this definitional issue first, as it is currently unclear whether FDA would accept a NDIN for a hemp extract product due to FDA's interpretation of the exclusionary clause as applied to CBD.

FDA Response to Citizen Petition

FDA's regulations require the agency to respond to a citizen petition within 180 days; however, a substantive response is not guaranteed in this timeframe. FDA's regulations permit the agency to provide a tentative response explaining why the agency has been unable to reach a decision on the petition – for example, due to the existence of other agency priorities, or a need for additional information. It is rare for FDA to provide a substantive response to a citizen petition within 180 days. Given the agency's priorities with the COVID-19 pandemic, it could be challenging for FDA to marshal the resources to provide even a tentative response within this timeframe.

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We will continue to monitor federal and state developments related to the marketing of hemp-derived ingredients, including CBD. If you have any questions on this or any other matter, please do not hesitate to contact us.