CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

July 16, 2019 submitted electronically via www.regulations.gov

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rom. 1061
Rockville, MD 20852

Re: **Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments**
Docket No. FDA-2019-N-1482; 84 Fed. Reg. 12969 (April 3, 2019)

Dear Sir or Madam:

In the April 3, 2019, *Federal Register*, the Food and Drug Administration invited both oral and written comments on the above-referenced notice regarding cannabis-derived compounds under the agency's jurisdiction.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements. Our mission is to empower self-care by preserving and expanding choice and availability of consumer healthcare products. As many dietary supplement products are being marketed as containing cannabidiol (CBD), CHPA has an interest in this subject and we presented oral comments at FDA's May 31, 2019, public hearing. These written comments supplement our oral remarks.

1. We share many of FDA's priorities for both OTC medicines and supplements: Public safety is paramount. Product quality must be ensured. Providing information to help consumers make informed choices is a role industry and government both share. These priorities apply to hemp-derived and CBD products in the same manner they would to other products under FDA's jurisdiction.

2. CHPA supports the status quo for ***medicines***: The existing new drug approval process provides a pathway for sponsors to develop data to bring cannabis-derived products to market once shown safe and effective. While all cannabis-derived medicines are available only with a prescription today, we see that process applying equally to prescription and nonprescription medicines should a sponsor have the data needed to support nonprescription use.

3. CHPA is well aware of the intense consumer and commercial interest in CBD and hemp-derived products more broadly. But we are very concerned that, with little regulatory oversight, the marketplace offers a vast array of products of varying degrees of quality, an array of unapproved drug claims, and in some cases, fraudulent products. As to fraud, for instance, as other speakers addressed at the May 31 public hearing, there are products sold directly to

consumers in the marketplace claiming to have certain levels of CBD, when in fact there may be no CBD, or CBD at multiples above that labeled in addition to THC. There are any number of products sold directly to consumers in the marketplace, both orally ingested and topical, making drug claims despite the lack of approval. While FDA has sent warning letters to firms making particularly egregious claims, we are not aware of any further enforcement activity against such claims. Further, despite the fact that FDA officials have stated CBD may not be legally marketed as a dietary supplement ingredient since it was first authorized for investigation as a new drug, dietary supplements marketed with CBD abound. This is in clear contravention of FDA regulation and law, and has the effect of penalizing law-abiding manufacturers in other FDA-regulated categories. More importantly, it may place consumers at risk.

In light of this situation, while FDA is charting a more comprehensive course forward, ***enforcement should increase***. For instance, the agency could issue more consumer alerts, or could play a greater role in raising public awareness about claims that are simply unsupported by data. Finally, FDA must go beyond warning letters to inspections, import reviews, and other enforcement actions. These would be important steps and utilize existing regulatory tools that do not require further legislative authority or rulemaking.

4. Beyond enforcement, the industry needs a path to bring CBD-containing dietary supplement products to market legally. One way to do that is for FDA to exercise its authority to exempt forms of CBD from the prior-investigational new drug/prior-new drug approval exception in the law's dietary supplement definition. Supplement makers would still need to file new dietary ingredient (NDI) notifications for CBD under this approach, so FDA would not need to predetermine the precise safe dietary supplement dose prior to proposing a rule for this path. Those filing NDI notifications would still need to meet the standard of sufficient information to provide reasonable assurance the ingredient does not present a significant or unreasonable risk. A second way to provide for dietary supplements would be to more narrowly define CBD for the purposes of the drug article versus supplement article distinction. We urge the agency to act on an exemption or develop another path ***this year***.

We appreciate the opportunity to provide these comments.

Sincerely,

David C. Spangler
Senior Vice President, Policy
& General Counsel

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