Congress of the United States
Washington, DC 20515

August 24, 2022

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf,

We write to express our disappointment with the technical assistance (TA) the Food and Drug Administration (FDA) provided on August 1, 2022 in response to our legislation, H.R. 6134, the CBD Product Safety and Standardization Act. This one-page TA, which took your agency nearly four months to provide in response to our request, is simply a reformatting of a document provided to Congress over two years ago, does not address provisions of our bill drafted specifically to address product safety, and is a completely insufficient response at this moment when cannabidiol (CBD) products are proliferating around the country. [1]

When Congress removed hemp-derived CBD from the Controlled Substances Act in the 2018 Farm Bill, it explicitly left to FDA the authority to set clear federal standards for safe human consumption of CBD products.[2] FDA has refused to act on that authority, allowing a marketplace where dangerous products, like those containing delta-8 THC, are often indistinguishable from products that meet strict standards for quality, dosage, packaging, and sale established by state regulators who have stepped in to fill the regulatory void.

Around two dozen states now have regulations governing the use of CBD in conventional food and beverage products or dietary supplements. States like New York and Minnesota have established comprehensive frameworks that license and regulate hemp farms and oversee the manufacturing, packaging, warehousing, and distribution of hemp products. They also set standards for appropriate use, dosage, and categories of products, including food and beverage, in which CBD can be used. These state regulations are a direct result of FDA's inaction, lack of clarity, and refusal to engage meaningfully on this issue. However, we believe that FDA can and should reverse course and learn from these state governments - working with them to determine how a federal framework could be designed to eliminate the unsustainable and inefficient patchwork of state regulations.

We understand FDA has called for more data and raised outstanding concerns about the safety of CBD. At the June meeting of FDA's scientific advisory board, the agency laid out their hesitancy to move forward with regulating CBD due to "numerous scientific gaps" in CBD research.[3] Waiting for perfect

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[1] See Attachment 1

[2] SEC. 10113 of the Agriculture Improvement Act of 2018 (PL-115-334):

"(c) EFFECT ON OTHER LAW.—Nothing in this subtitle shall affect or modify—
(1) the Federal Food, Drug, and Cosmetic Act (21 U.S.C.301 et seq.);
(2) section 351 of the Public Health Service Act (42 U.S.C.262); or
(3) the authority of the Commissioner of Food and Drugs and the Secretary of Health and Human Services—
(A) under—
(i) the Federal Food, Drug, and Cosmetic Act (21U.S.C. 301 et seq.); or
(ii) section 351 of the Public Health Service Act " (42 U.S.C. 262); or
(B) to promulgate Federal regulations and guidelines that relate to the production of hemp under the Act described in subparagraph (A)(i) or the section described in subparagraph (A)(ii).

[3] https://www.fda.gov/advisory-committees/science-board-food-and-drug-administration/background-materials-june-14-2022-meeting-science-board-fda

answers to every conceivable question before taking any steps to establish a federal regulatory framework is unacceptable. Regulatory bodies in peer countries, including Australia and Japan, have established structured regulatory frameworks to ensure products on the market meet basic consumer expectations of quality. At a minimum, FDA should be developing a rational public enforcement discretion policy articulating specific circumstances in which the agency will prioritize enforcement actions until such a framework is in place.

We share the frustration you voiced at a recent Congressional hearing about working on CBD policy during your previous tenure at the agency in 2016 and that "in 2022 it looks pretty much the same in terms of where we are" and "when you come back six years later to the job you had before and nothing has really changed, that is telling you that you can't just keep trying to do the same thing over and over."[4]

In your testimony, you committed to working with Congress to "come up with something new" based on your view that "the current authorities [FDA has] on the food side and on the drug side do not necessarily give [FDA] what [you] need to have to get the right pathways moving forward." We have been eagerly awaiting FDA's response to our request for TA for some time in hopes that we could constructively engage with you, per your recent testimony, on an amenable path forward.

We worked hard to craft a bill that would provide the agency with tailored authorities to address the concerns FDA has raised in order to establish a workable, responsible framework for the regulation of hemp-derived CBD in conventional food products:

- The bill exempts hemp-derived CBD from a provision within section 301 of the Food, Drug, and Cosmetics Act (FD&C Act) that prohibits the inclusion of ingredients in conventional food products that were previously approved as drugs. The TA notes that "for CBD to be added to a conventional food product, it would first need to be approved as a food additive in accordance with section 409 of the FD&C Act" but says nothing about section 301. We would also like to see product manufacturers willing and able to avail themselves of the regulatory pathways available to all other new food ingredients; however, absent CBD being removed from the section 301 prohibition, it is very unclear how and why they would.
- The bill specifically charges FDA with promulgating regulations to establish requirements for labeling, packaging, serving limits, and conditions of use (which include limiting food categories) for CBD as a food additive. FDA in fact already has this authority pursuant to section 409(d) of the FD&C Act and has, similar to the authorities under section 301, failed to use it.[5] The issuance of regulations regarding these issues should address the following concerns raised in FDA's TA–
    - *Vulnerable populations/Accidental ingestion*. FDA has noted several times concerns about ingestion of CBD by children, the elderly, pregnant and lactating women, and those with chronic illness.
        - Under our legislation, it would be in FDA's clear purview to regulate how the products are packaged and labeled – so consumers would know a product contains CBD just by looking at it on the store shelf. FDA would also have the authority to limit the products CBD could be used in to reduce the risk of unintended consumption. For instance, the agency could clarify that CBD could not be used in certain established food categories that children regularly eat, such

[4] https://appropriations.house.gov/events/hearings/agriculture-hearing-fda-commissioner-robert-m-califf-md

[5] 21 U.S. Code § 348 "…(d) Regulation issued on Secretary's initiative. The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal…"

as "Breakfast cereals, including ready-to-east instant and regular hot cereals"[6] or "Frozen dairy desserts…"[7]

- *Displacement of medical care*. We agree that any manufacturer of a CBD product making drug claims should be held accountable under FDA's current drug authorities. However, FDA's assertion that creating a regulatory pathway for CBD-containing food products will drive patients to "use CBD-containing foods in lieu of approved drugs, and may delay seeking needed medical care" is disingenuous at best.

  First, a robust market of CBD-containing products exists today – effectively unregulated by the FDA. These products are not required to follow Current Good Manufacturing Practice standards, dosage limits, and in many cases are marketed with dubious medical claims.

  Second, the amount of CBD found in products currently marketed in the conventional food and beverage space is a tiny fraction of that found in FDA approved CBD products for seizures. For instance, the FDA-approved dosing for Epidiolex is 5-20mg/kg/day. Several market-leading beverages contain 10-20mg of CBD per 12oz can. An average 70kg adult would therefore need to consume a minimum of 14 cans per day to reach a starting dose, notwithstanding that the low concentration of CBD compared to the drug product would drastically change the pharmacology of the product. With appropriate serving size limits and clear labeling of both the amount of CBD and any other disclaimers the FDA deems appropriate, there would be drastically less confusion about the medical benefits of CBD outside of regulated drugs. If anything, leaving this market untouched exacerbates the two main problems FDA claims to be trying to solve.

We were genuinely hopeful that, even if some in the agency disagreed with the particulars, you, as Commissioner, would have viewed our legislation as an opportunity to jumpstart a productive dialogue and make up for lost time.

We respectfully request the following within 30 days:

1. A new TA document that addresses the actual text and construct of our bill.

2. A redline to our legislative language, or new legislative language, that establishes a *pathway* for CBD to be legally marketed in food products and provides the appropriate safety considerations.

3. A public charge to the Reagan Udall Foundation that, as part of the internal review of CFSAN they are conducting per your request, TA processes (including clearance processes) be assessed as part of the report, using CBD as an example.

4. An update on any ongoing work at the agency to develop an enforcement discretion policy articulating specific circumstances in which the agency will prioritize enforcement actions against CBD products. If no work is ongoing, please provide an explanation for why not.

5. Answers to the following questions

   a. What are the specific discrete scientific questions FDA is seeking answers to before issuing regulations to permit CBD in food and other products?

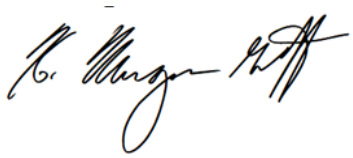
[6] 21 CFR § 170.3(n)(4)
[7] 21 CFR § 170.3(n)(20)

i. What actions has FDA taken to present these questions to the scientific community?
ii. What other actions has FDA taken to obtain answers to these questions?
iii. Does FDA have answers to these questions for every other food ingredient and dietary supplement ingredient on the market? If not, please explain the difference in standards.

b. Has FDA spoken with any state and international regulators to learn about the information and policy considerations used to set regulations for CBD-containing food products in these jurisdictions? If so, please provide the participants and dates of these meetings and the agendas. If not, please provide the rationale for not doing so.

Sincerely,

Kathleen M. Rice
Member of Congress



H. Morgan Griffith
Member of Congress

Angie Craig
Member of Congress

Dan Crenshaw
Member of Congress

Attachment 1

Highlighted text in the TA provided to our office on August 1, 2022 represents the portions taken verbatim from the TA provided to the Senate HELP Committee on July 23, 2020.

U.S. FOOD & DRUG ADMINISTRATION

FDA Comments on CBD Product Safety and Standardization Act

Provided to the staff of Representative Rice on 8/1/2022

These comments are intended only to provide technical assistance and are by no means to be interpreted as any kind of approval or endorsement of the legislation by the Department of Health and Human Services and its agencies or the Administration.

General Comments:

The proposed bill language as it stands now raises important public health and operational considerations.

Consumers, including vulnerable populations such as children, the elderly, those who are pregnant and lactating, and those with chronic illnesses, will be put at risk if Congress requires the Agency to allow CBD broadly into the food supply at any threshold level despite a lack of adequate safety data or sufficient regulatory safeguards to control risks. The available data indicate that CBD is associated with risks such as liver toxicity, drug-drug interactions, and male reproductive toxicity, which suggests that long-term CBD consumption may be harmful for the general population and for sensitive sub-populations. Furthermore, FDA would be very limited in its authority and resources to oversee many of the products that might be allowed. We would face significant challenges in preventing and responding to adverse public health consequences were this language to be enacted. Information on these safety concerns can be accessed on our website: https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis

Further, given the unsubstantiated claims of CBD's utility in a wide variety of conditions for which it has not found to be safe and effective, FDA is concerned that patients may try to use CBD-containing foods in lieu of approved drugs, and may delay seeking needed medical care.

We understand the intent of the language is to enable CBD to be added to conventional food products. However, for CBD to be added to a conventional food product, it would first need to be approved as a food additive in accordance with section 409 of the FD&C Act. At this time, FDA has not approved CBD for any use as a food additive, and FDA has concerns regarding the safety implications of introducing CBD into the mainstream food supply, including risks to sensitive populations like children and those who are pregnant or nursing. We are not aware of evidence showing that CBD is generally recognized as safe (GRAS). To the contrary, as noted above we are aware that CBD is associated with risks. For this reason, there are scientific questions regarding whether CBD could meet the safety standard for food additive approvals. It is thus unclear whether the effect of the sponsor's language would be that CBD could be added lawfully to conventional foods.