NIHC
NATIONAL INDUSTRIAL HEMP COUNCIL

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U.S. Food and Drug Administration

Docket ID: FDA-2019-N-1482

Dear Members of FDA's CBD Working Group:

Thank you for your time discussing our perspective recently during our listening session on July 27, 2020. We appreciated the opportunity for members of our Consumer Protection Task Force to present our views and we submit these specific recommendations to help guide your work on establishing a robust policy of enforcement discretion for cannabidiol (CBD) products.

We would like to start by thanking you for your work over the last several months in developing a policy of enforcement discretion, which we hope can be very helpful to advance our industry in a way that protects consumers. We know that it takes time to establish an appropriate policy and we appreciate your thoughtful approach.

NIHC members support safety standards for our industry. We are well aware of the reports of inconsistent products that do not contain the ingredients listed on the label, those that feature unsubstantiated health claims, or which contain excessive THC levels or other contaminants. Our mission is to help advance the hemp industry through safe, reliably manufactured products that consumers can rely on and we're glad to partner with FDA to bring this to fruition.

There are five critical issues that we believe should be included in FDA's analysis and Enforcement Discretion Policy. These are as follows:

1. Existing studies support safety of human consumption of CBD in dosing appropriate for dietary supplements and conventional foods.

As a foundational matter, in approving the drug EPIDIOLEX®, the FDA has recognized safety in human consumption of CBD and high doses for children with highly compromised health, most of whom are also taking multiple other drugs along with CBD. The EPIDIOLEX® studies recognize safety and little to no liver toxicity at 10 mg/kg/day in children, which equates to at least 700 mg/kg/day in adults. Those children showing any adverse toxic effects at a 20 mg/kg/day doses were primarily patients on concomitant valproate, a risk which can be effectively managed under

existing drug-drug interaction warning requirements for dietary supplements, e.g. St. John's Wort. Other studies on healthy adults support no adverse reactions at doses of more than 1000mg/day.

Given that CBD consumption in dietary supplements and conventional foods will be much lower concentrations and marketed toward healthy adult consumer populations, existing FDA laws and regulations for dietary supplements and conventional foods are sufficient to ensure good manufacturing practices, accurate claims, and labeling standards addressing drug-drug interaction, recommended daily dose, and any other warnings needed as supported by science. The FDA has effectively regulated other dietary ingredients and food additives similar to, and in some cases without the proven safety profile of, CBD.

2. FDA should continue to allow marketing and sale of CBD cosmetics while it investigates CBD consumption's systemic impact on humans.

The FDA's current position on CBD cosmetics, that CBD is not prohibited or restricted as a cosmetic ingredient[1] while it continues its evaluation of CBD's systemic impact on humans is supported by studies indicating that topical administration of CBD does not break the human blood-barrier in significant measurement. One study submitted to FDA's public docket by NIHC member Canopy Growth Corporation on August 13, 2020 in response to Request for Comments Docket No. FDA-2019-N-1482; 84 Fed. Reg. 12969 (April 3, 2019), specifically assessing topical administration of CBD, concludes:

> …. that the topical formulations provide extensive skin absorption and would be good candidates for local delivery of CBD to muscle, joint, or nerve tissues but would not provide significant systemic levels of CBD due to the limited and gradual transdermal flux of CBD observed in the human skin samples.

Accordingly, topical administration of CBD is not relevant to FDA's stated concerns and goals in assessing systemic impacts of CBD consumption, including, without limitation, liver and reproductive toxicity. Conversely, reversing the FDA's current position regarding CBD cosmetics would inflict immediate and severe adverse impacts on the hemp industry and conventional online and brick-and-mortar retail, e.g. Sephora, Alta, Target, all of whom have materially relied on the FDA's current guidance to build commercial strategies.

3. Clarity regarding standardized testing requirements and laboratory practices.

Concern exists that manufacturers, processors, and laboratories are not clear on best practices for testing, traceability, or production. This creates safety concerns throughout the supply chain

[1] fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#cosmetics

and for consumers. Mandatory compliance testing for contaminants that are unsafe for consumption will help ensure safe products and transparency.

Laboratories with experience in hemp testing and the testing of various hemp derived and extracted products have voiced strong concern over the lack of industry standard retail product testing. Because transparency with consumers is not an industry practice uniform in the production of hemp retail products, this creates the ability for some producers to claim safety without actually testing for the contaminants that would render a product unsafe or adulterated. Mandatory compliance testing for contaminants unsafe for human consumption will set the framework that will immediately separate the companies that aim for safe compliant products and those who try to only contribute the minimum amount of integrity to the industry.

We recognize the challenge of creating a national standard given variances in pesticide usage by state, the potential for off-label pesticide use and contamination originating from environmental pollution. However, experienced hemp and cannabis laboratories accredited in their respective markets per ISO: 17025:2017 have been an integral part of demonstrating the safety of many CBD products. Most active hemp laboratories focus on retail education and awareness efforts for strict testing requirements including data submission detailing reasonable, detectable action limits for Residual Solvents, Pesticides, Heavy Metals and Microbiological Contaminants. We reviewed FDA's RFQ for lab services published August 13, 2020 and agree with the agency's apparent expectations for use of robust and reliable test methodologies. We encourage FDA to provide the necessary guidance to establish uniform best practices regarding testing.

In addition, we encourage FDA to coordinate with U.S. Customs and Border Protection to enhance inspections at U.S. ports to help identify foreign product that may be misbranded or adulterated. Domestic producers that invest in compliance should not be disadvantaged by foreign producers who are able to evade detection. Particular concern has been raised regarding the presence of lead-based paint in Chinese manufactured bottles and droppers which have been found to cause high lead tests. CBD manufacturers should be required and educated on the importance of using food grade containers to prevent such contamination.

4. Standardized national manufacturing and labeling requirements for product transparency.

The state-by-state labeling patchwork that has developed over the past year and a half is creating an unworkable compliance scenario. The discussion below details suggested manufacturing and labeling requirements to establish a stable and consistent national regulatory environment by including the following elements. We would point to current regulations in Florida and proposed regulations in Colorado as models for national adoption.

- The product is sourced in a manner compliant with the 2018 Farm Bill.

- Extraction, manufacturing, processing, and testing are conducted in compliance with good manufacturing practices and/or a recognized third-party quality standard, e.g., ISO 22000 for an edible product cGMP, AOAC and ISO 17025:2017
- The products have a Certificate of Analysis (COA) prepared by an independent testing laboratory that states:
  - 1. The hemp extract is the product of a batch tested by the independent testing laboratory;
  - 2. The sample contained a total delta-9-tetrahydrocannabinol concentration that did not exceed 0.3 percent on a dry-weight basis pursuant to the testing of a random sample of the batch; and
  - 3. The sample taken from batch (ID) does not contain contaminants at levels that exceed the levels detailed in (regulation 1), (regulation 2) and (regulation 3).
    - Independent testing laboratory means a laboratory that is, among other things, "accredited by a third-party accrediting body as a competent testing laboratory pursuant to ISO/IEC 17025 of the International Organization for Standardization." ISO/IEC 17025 is the international standard for testing and calibration laboratories.
    - Define "contaminant" to include, but not be limited to, "any microbe, fungus, yeast, mildew, herbicide, pesticide, fungicide, residual solvent, metal, or other contaminant found in any amount that exceeds any of the accepted limitations as determined by rules … or other limitation pursuant to the laws of this state, whichever amount is less."

- The products comply with federal food, dietary supplement, or cosmetic labeling standards, as applicable.
- The products accurately disclose the cannabinoid and CBD levels per product or per dosage within the variances allowed for foods and dietary supplements. If the products are hemp-based but do not contain CBD, this should be affirmatively disclosed, e.g., a hemp seed oil would require a disclosure that the product does not contain CBD.
  - The products feature the following disclosures: "This product has not been evaluated by the Food and Drug Administration." "This product should not be used to diagnose, treat, cure, or prevent any disease or condition." "Talk to your doctor about all CBD products you are using." "Consult a physician before starting a CBD regimen."

- The products feature a warning that advises against use by pregnant or nursing women, children under age 18, or individuals taking prescription medications absent consultation with a doctor.
- The products do not feature any health benefit claims that could not otherwise be made on a food, dietary supplement, or cosmetic (as applicable) pursuant to federal standards.
- The product features a QR code that links to:

    1. The product certificate of analysis of the hemp extract by an independent testing laboratory;

    2. The batch number;

    3. The Internet address of a website where batch information may be obtained;

    4. The expiration date; and

    5. The number of milligrams of hemp extract.

5. Definitions for key terms, e.g., "broad spectrum," "hemp extract," etc.

There are currently no standardized terms for the varying types of hemp extract available, e.g., "broad spectrum," "hemp extract," "hemp oil," etc. Without this, it is impossible for consumers to know exactly what they are purchasing. We welcome standardization of these terms to promote uniform labeling, marketing, and transparency.

Further, acknowledging or assigning what cannabinoids will be relevant to the FDA enforcement program would be helpful as cannabis science develops and new cannabinoids are commercialized. Further, this creates confusion as to properly judging potency, e.g., does FDA recognize "Multi-Spectrum" "Broad Spectrum" "Isolate" on CBD marketed products as separately judged potency calculations?

There are real-world ramifications of not having standardized definitions. For example, many CBD companies market a full spectrum product, which implies the product has multiple cannabinoids plus the presence of THC, along with a broad spectrum product which indicates that the THC has been removed to untraceable levels. This is a way of expressing to consumers that a product may or may not contain THC. However, drug screens may not all be able to separate THC from CBD, instead looking for the cannabis molecule as a whole, and resulting in a positive drug test. Until drug screens are updated to differentiate or eliminate, this will remain a concern with retail products and consumer understanding of what possible detectable analytes could be present after use.

* * *

We believe that including these points in a policy of enforcement discretion would provide clear guidance for industry regarding FDA's expectations for manufacturing and labeling CBD products. We understand that FDA is continuing to review data and safety considerations regarding the impact of cumulative CBD use and consumption and that further clinical research may be needed to confirm the health benefits or hazards that may be associated with CBD. We support this work. However, at present, industry and consumers need FDA to issue guidance to ensure a marketplace that is as safe as it can be. These requirements strike the right balance between protecting consumers and providing guidance to industry.

We thank FDA and, in particular, the CBD Working Group for its hard work and we look forward to working together in the future.

Sincerely,

Patrick Atagi
Board Chairman

Copies to:

White House Office of Management and Budget

U.S. Customs and Border Protection