U.S. Hemp Roundtable

202.292.4147 | info@hempsupporter.com
20 F Street NW, Suite 850, Washington, DC 20001

VIA EMAIL

May 23, 2022

Dr. Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf,

The U.S. Hemp Roundtable, the hemp industry's national advocacy organization, was pleased to see your testimony last week before the House Appropriations Committee. We share your frustration that nothing has been accomplished by FDA regarding CBD in the six years since you last served as Commissioner, and we appreciate your repeated commitment to identify additional pathways for CBD.

You expressed the need to identify a creative approach to this complex issue. While FDA determines the appropriate next steps, we would like to offer an interim solution, based on FDA's recent announcement of its intent to exercise enforcement discretion with respect to the sale and distribution of certain products that contain N-acetyl-L-cysteine (NAC) and are labeled as dietary supplements, and its consideration of a rulemaking to allow the use of NAC in dietary supplements.

Today, we ask FDA to take these same actions for dietary supplements that contain legal hemp-derived cannabidiol (CBD) and other lawful hemp ingredients, especially in light of new safety data on CBD discussed below. Although this letter is focused on dietary supplements, we also renew our call for FDA to establish a pathway for the inclusion of CBD and other hemp ingredients in foods and beverages.

FDA has stated that NAC and CBD are both "articles" that were either approved or studied as drug prior to being marketed in a dietary supplement or a food, and are therefore excluded from the definition of "dietary supplement" under section 201(ff)(3)(B) of the FD&C Act. However, the law also authorizes FDA to issue a regulation finding that such articles are not excluded from this definition, which FDA is considering for NAC. FDA's draft guidance on NAC provides that a policy of enforcement discretion would apply to products that would be lawfully marketed dietary supplements, if NAC were not excluded from the definition of "dietary supplement," and that are not otherwise in violation of the FD&C Act.

The Roundtable requests that FDA take the same incremental steps for CBD and issue a similar policy of enforcement discretion for dietary supplements that contain CBD**.** We also request that the Agency consider a rulemaking to provide that CBD is lawful in dietary supplements. Given the growing body of safety data on CBD, we also emphasize the need for FDA to work collaboratively with the scientific community and effectively utilize this data to advance policy on CBD.

We recognize that safety was a factor in FDA's decision to issue the draft guidance on NAC and agree that safety should always guide FDA policy. Indeed, there has been no indication that CBD poses significant safety concerns at the levels typically found in CBD dietary supplements, based on adverse event reporting, observational data, and toxicology data on CBD. In December 2021, yet another toxicology study on CBD-containing hemp extract was published that further demonstrates its strong safety profile, and we expect additional toxicology data to be published in the coming months. Further, on March 22, 2022, Validcare completed the second phase of its CBD safety study, which includes observational data from an additional 200+ participants, thereby strengthening the statistical reliability of the results. The Validcare study provides data that addresses FDA's specific safety concerns regarding CBD, with the results indicating that daily CBD consumption across a range of typical retail products and serving sizes is not associated with elevated liver tests, low testosterone levels, or daytime drowsiness.

It has been over four years since the 2018 Farm Bill legalized hemp and non-intoxicating hemp derivatives like CBD. Within hours of the Farm Bill's signing, then-FDA Commissioner Scott Gottlieb recognized the "clear interest of Congress in fostering the development of appropriate hemp products" and acknowledged that the FDA "has the authority to issue a regulation," which would allow for the lawful marketing of CBD as a dietary supplement. Since that time, thousands of consumers have relied on CBD-containing dietary supplements to support their health and wellness.

Unfortunately, FDA has taken no concrete steps toward regulation in the intervening years. In September 2021, then-Interim FDA Commissioner Dr. Janet Woodcock reversed course and argued that the law is "fairly clear," barring the agency from further action on CBD and putting the agency in a "stalemate position." However, FDA's actions on NAC prove there is in fact an opportunity to pave a pathway forward for CBD – with a policy of enforcement discretion being the needed first step.

Indeed, a real health and safety issue for American consumers is posed by the status quo, which has contributed to an unregulated marketplace. As outlined in a recent letter authored by Representative James Comer, products that are improperly sold as legal hemp continue to proliferate, posing a clear public health threat. We share Rep. Comer's concerns and agree that action by Congress and FDA is urgently needed to help protect consumers from unsafe, intoxicating products.

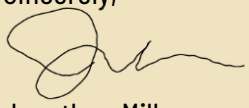
Consumers and the hemp industry are waiting for decisive federal action on CBD, and we once again urge FDA to take steps toward the legalization of CBD. We also urge FDA to include other non-intoxicating hemp derivatives in any such regulatory actions, as scientific interest in other hemp compounds continues to increase, and the pharmaceutical industry should not have a monopoly on these ingredients. When

manufactured, labeled, and marketed in accordance with federal requirements, dietary supplements that contain hemp-derived ingredients are safe and non-intoxicating. We also support FDA's efforts to target delta-8 THC and similar products that put consumers and children in particular at risk. Increased enforcement against such products together with a clear policy of enforcement discretion for CBD and other non-intoxicating hemp products will significantly improve the marketplace for consumers and industry alike.

We ask you to take immediate action to issue an enforcement discretion policy for CBD and other lawful hemp-derived products, similar to your actions on NAC, to help pave a regulatory pathway for these products. We also request a meeting with the FDA Cannabis Products Committee to discuss this and the recent safety data on CBD discussed above, including the newly released Validcare results, to understand how FDA intends to utilize this data and what data gaps remain.

Finally, you suggested at the hearing that Congress needs to do more on this issue. We strongly agree, and have been urging Congress to pass HR 841, HR 6134 and S 1698 to ensure that hemp-derived extracts like CBD are regulated as dietary supplements and food and beverage ingredients. We are open to other creative solutions like you suggest and have been willing for the past three years to sit down with FDA to discuss alternative approaches. Unfortunately, the agency has been unwilling to meet with us to discuss legislative options. At the same time, we have been told FDA is urging congressional staff not to proceed with existing legislation. We ask for your help to break this stalemate, and we stand by to participate in productive negotiations with your staff to come up with solutions that best protect American consumers.

Sincerely,



Jonathan Miller
General Counsel
U.S. Hemp Roundtable

Cc: Dr. Janet Woodcock, FDA Principal Deputy Commissioner, FDA Cannabis Products Committee

Paid for by U.S. Hemp Roundtable, Inc., an independent, nonprofit organization exempt from federal taxation under section 501(c)(4) of the Internal Revenue Code.
www.hempsupporter.com

2022 U.S. HEMP ROUNDTABLE

EXECUTIVE COMMITTEE

ANANDA HEMP/ECOFIBRE
CRONOS GROUP
CURALEAF
GARDEN OF LIFE
MEDTERRA
TURNING POINT BRANDS

BOARD OF DIRECTORS

AMERICAN SHAMAN
ANANDA HEMP/ ECOFIBRE
CANOPY GROWTH CORPORATION
CBDISTILLERY
CRONOS GROUP
CURALEAF
GARDEN OF LIFE
HEMP INDUSTRIES ASSOCIATION
KOI CBD
MEDTERRA
RED MESA SCIENCE AND REFINING
TURNING POINT BRANDS
U.S. HEMP AUTHORITY
VERGE AGRITECH
ZILIS

MEMBERS

ACCELERATE 360
ALLIANCE FOR NATURAL HEALTH USA*
AMERICANS FOR SAFE ACCESS*
AMERICAN HERBAL PRODUCTS ASSOCIATION*
AMERICAN SHAMAN
ANANDA HEMP/ ECOFIBRE
ANCIENT NUTRITION
ASSOCIATION OF WESTERN HEMP PROFESSIONALS*
BARLEAN'S
BLUEBIRD BOTANICALS
BOTANACOR LABORATORIES
CALIFORNIA HEMP COUNCIL*
CANOPY GROWTH CORPORATION
CBDISTILLERY
CBDMD
CONSUMER HEALTHCARE PRODUCTS ASSOCIATION*
COUNCIL FOR RESPONSIBLE NUTRITION*
CRONOS GROUP
CURALEAF
CV SCIENCES
DEX SUSTAINABLES
ELIXINOL
ESQUIRE BANK
EUROFINS FOOD INTEGRITY AND INNOVATION
EVG EXTRACTS
FLEX PAYMENT SOLUTIONS
FRIENDS OF HEMP*
GARDEN OF LIFE
GVB BIOPHARMA
HARROD'S CREEK FARM
HEMP ALLIANCE OF TENNESSEE*
HEMP INDUSTRIES ASSOCIATION*
HEMPSI
HIGH TIDE
INDIGENOUS PRODUCTION TRADE ALLIANCE*
KANNACO
KANNAWAY
KOI CBD
M&C COMMUNICATIONS
MEDTERRA
MIDWEST HEMP COUNCIL*
NATIONAL CANNABIS INDUSTRY ASSOCIATION*
NATIONAL ANIMAL SUPPLEMENT COUNCIL*
NEW LEAF DATA SERVICES
PRESENCE MARKETING
PRIORITY PAYMENT SYSTEMS
RADICLE SCIENCE
REALM OF CARING*
RED MESA SCIENCE AND REFINING
SPARTAN SWORD*
TEXAS HEMP COALITION
TURNING POINT BRANDS
UNITED NATURAL PRODUCTS ALLIANCE*
U.S. HEMP AUTHORITY*
U.S. HEMP BUILDING ASSOCIATION*
VERGE AGRITECH
VETERINARY CANNABIS SOCIETY*
VIRGINIA HEMP COALITION*
WE ARE FOR BETTER ALTERNATIVES
WISCONSIN HEMP ALLIANCE*
WYLD
ZILIS

**DENOTES NON-PROFIT ADVOCACY PARTNER*

Paid for by U.S. Hemp Roundtable, Inc., an independent, nonprofit organization exempt from federal taxation under section 501(c)(4) of the Internal Revenue Code.
www.hempsupporter.com