U.S. Hemp Roundtable

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

VIA EMAIL

September 17, 2021

Elizabeth A. Char, MD
Director of Health
Hawaii Department of Health
1250 Punchbowl Street
Honolulu, Hawaii 96813

Dr. Char:

The U.S. Hemp Roundtable, the hemp industry's national advocacy organization, appreciates your leadership in monitoring hemp processing and the sale of hemp products. We strongly support your mission ensuring the provision of safe hemp and CBD products to Hawaii consumers. We understand that this was your primary objective in your recent promulgation of interim rules for hemp processing and hemp products (Chapter 11-37).

While most of your regulations are appropriate and consistent with the laws and regulations of federal and state governments, some others conflict with federal standards, are unduly burdensome to Hawaiian farmers and product manufacturers, and/or are unaligned with the Department of Health's commitment to protect public health and safety. We identify below sections in the interim rules that are of particular concern. We ask that the Department of Health consider addressing these concerns before the interim rules take final form.

1. Section 11-37-3(a)(1)

Subsection (a)(1) requires the statement "Use this product under the guidance of a physician if you have a medical condition or are pregnant or lactating." However, it does not provide any flexibility, for example, if a company chooses to use a similar statement, such as "Consult a physician or healthcare professional if you have a medical condition or are pregnant or lactating." These alternatives would not be permitted under the interim rules as drafted, and companies would be forced to unnecessarily relabel their products. Therefore, we recommend the following change:

The statement **or a similar statement** "Use this product under the guidance of a physician if you have a medical condition or are pregnant or lactating."

2. Section 11-37-3(b)

Section 11-37-3(b) prohibits "any hemp product that does not meet the testing requirements in subchapter 2." Some aspects of the testing requirements are specific to Hawaii. For example, they require that testing "be conducted by a laboratory facility that is accredited to the ISO/IEC 17025:2017 standard, "General requirements for the competence of testing and calibration laboratories, by an accreditation organization recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition

Arrangement." However, the interim rules also require lab reports of test results to include a certification by lab staff that must be completed at the time of performance and establishes compliance with test methodology and QA standards. While some states require ISO/IEC 17025:2017 status, we are not aware of any state that requires this additional and burdensome certification, and not every state imposes this ISO/IEC accreditation requirement.

Nor does the U.S. Department of Agriculture's (USDA) Final Rule on Establishment of a Domestic Hemp Production Program, which became effective January 19, 2021. While USDA's Agricultural Marketing Service "strongly encourages laboratories to be accredited to ISO/IEC 17025 (by an International Laboratory Accreditation Cooperation Mutual Recognition Agreement (ILAC MRA signatory accreditation body)," it acknowledges that such accreditation can be challenging, time-consuming, and costly. For those reasons, USDA elected to not adopt a requirement that hemp testing laboratories be approved under a USDA Laboratory Approval Program or undergo ISO accreditation. Hawaii should follow USDA's lead. In the event the Department of Health retains an accreditation requirement, we request that it be broadened to allow for testing by any duly accredited laboratory.

Further, section 11-37-3(b) does not contemplate hemp products that undergo testing in a state with testing requirements that are substantially similar to those in subchapter 2. We request that section 11-37-3(b) be amened to allow hemp products that meet subchapter 2's testing requirements **or** substantially similar testing requirements of another jurisdiction. This change would be similar to the accommodation made in interim rule section 11-37-50, which allows hemp processors to source hemp from a hemp producer with a license from any state with a USDA-approved hemp plan.

3. Section 11-37-3(d)

Section 11-37-3(d) states, "No person shall sell, hold for sale, offer, or distribute any hemp product intended to be consumed orally . . ." Similarly, section 11-37-3(e) provides, "No person shall sell, hold for sale, offer, or distribute any food, as defined in section 328-1, into which a cannabinoid, synthetic cannabinoid, hemp extract, hemp derivatives, or other hemp product has been added as an ingredient or component." Together, these subsections seem designed to embrace the U.S. Food and Drug Administration's (FDA) guidance regarding adding cannabidiol (CBD) to food and marketing CBD as a dietary supplement (i.e., orally consumed products). To be clear, we disagree with the FDA's guidance as a legal and factual matter. But the guidance is limited to CBD. We are not aware of any FDA guidance with respect to other hemp cannabinoids in ingestible hemp products. Accordingly, sections 11-37-3(d) and 11-37-3(e) are overbroad and sweep up hemp products that even the FDA does not disfavor.

If Hawaii is going to attempt to follow the FDA's guidance on CBD, we request that sections 11-37-3(d) and 11-37-3(e) be narrowed to prohibit only hemp products **that contain CBD**.

4. Section 11-37-3(j)

Section 11-37-3(j) states, "Except for hemp products intended for external topical application to the skin or hair, no person shall sell, hold for sale, offer, or distribute any products containing hemp or hemp derivatives that are intended to be introduced via non-oral routes of entry to the body, including but not limited to, use in eyes, ears, and nasal cavities." While the rule may be well-intended to prohibit hemp products directly administered non-orally, such as eye drops, ear drops, or nasal sprays, it has the consequence of prohibiting aromatic and home good hemp products that are not topically applied, including candles, essential oils, fragrant sprays, and incense. We request that the rule be made clearer to exclude non-topical products that are not directly administered via non-oral routes.

5. Section 11-37-30

Multiple changes to section 11-37-30's labeling requirements are needed to better align with existing state and federal requirements. Subsection (a)(11) requires the statement "This product has been tested pursuant to chapter 11-37 subchapter 2, Hawaii Administrative Rules." This is a Hawaii-specific statement that no other state requires. While we appreciate that subsection (d)

provides some exception, which allows this statement to be included on labeling attached to or inserted into the package, companies will still be required to print and include special inserts only for hemp products distributed in Hawaii, which is unnecessarily costly and creates significant supply chain challenges.

Subsection (b)(1) states, "Except as provided in subsection (d), every hemp product intended to be consumed shall be labeled with the following information displayed prominently and conspicuously, but in no case may the letters or numbers be less than one-sixteenth inch in height . . . The statement 'This product is not intended to diagnose, treat, cure, or prevent any disease.'" The statement is problematic because it requires only part of the FDA's required disclaimer for dietary supplement structure/function claims under FDA regulation. Specifically, 21 CFR 101.93(c) requires the following statements on dietary supplement labels, if the supplement makes a structure/function claim, which must be linked to the claim with a symbol, among other requirements listed in the regulation: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Therefore, a dietary supplement that strictly complies with section 11-37-30(b)(1) may be in violation of federal law. For this reason, subsection (b)(1) should be removed from the rules, or simply require hemp products labeled as dietary supplements and that make structure/function claims to comply with 21 CFR 101.93.

Subsection (b)(2) requires that hemp products be labeled with the "The net quantity (in terms of weight, measure, or numerical count) of each serving and the total delta-9 tetrahydrocannabinol and cannabidiol content (in milligrams) per serving[.]" We disagree with mandatory labeling of delta-9 THC in milligrams, but this requirement also raises concerns because it incorrectly uses the term "net quantity" in reference to individual servings of ingredients in a product. Rather, FDA regulations refer to "net quantity" as the net quantity within an *entire* product. Therefore, we request that subsection (b)(2) be changed as follows:

The net quantity (in terms of weight, measure, or numerical count) **of the product, and the quantitative amount** of each serving and the total delta-9 tetrahydrocannabinol and cannabidiol content (in milligrams) per serving.

Finally, section 11-37-30(c) does not appear to reflect all exemptions and requirements provided under FDA regulations, which could lead to industry and consumer confusion. We request that the section be deleted.

6. Sections 11-37-31 and 11-37-32

Like section 11-37-30(c), sections 11-37-31 and 11-37-32 do not appear to be entirely consistent with FDA labeling requirements. We request that these sections not prescribe specific requirements, but instead require ingredient and responsibility statements to be compliant with federal regulations, specifically 21 CFR Parts 101 (dietary supplements) and 701 (cosmetics).

We appreciate your consideration of these requests and welcome the opportunity to speak to you in further detail about the importance of these changes to Hawaii's hemp industry.

Sincerely,

Jonathan Miller
General Counsel
U.S. Hemp Roundtable

2021 U.S. HEMP ROUNDTABLE

EXECUTIVE COMMITTEE

ANANDA HEMP
CANOPY GROWTH USA
CRONOS GROUP
CV SCIENCES
ELIXINOL
GARDEN OF LIFE
HEMPFUSION
MEDTERRA
PET RELEAF
TURNING POINT BRANDS

BOARD OF DIRECTORS

AMERICAN SHAMAN
BALANCED HEALTH BOTANICALS
BOTANACOR
CURALEAF
FRONT RANGE BIOSCIENCES
GREEN ROCK HEMP HOLDINGS
HEMPWORX
HEMP INDUSTRIES ASSOCIATION
KOI CBD
NUSACHI
RECESS
U.S. HEMP AUTHORITY
VILLAGE FARMS
ZILIS

MEMBERS

ACCELERATE 360
ALLIANT INSURANCE SERVICES
ANCIENT NUTRITION
APAX
BARLEAN'S
BENEFICIAL BLENDS
BLUEBIRD BOTANICALS
BMJ GROUP
BOLDT RUNNERS CORPORATION
CALIPER FOODS
THE CBDISTILLERY
CBDMD
CRITICALITY
ELEGANCE BRANDS
ESQUIRE BANK
EUROFINS FOOD INTEGRITY AND INNOVATION
EVG EXTRACTS
FLEX PAYMENT SOLUTIONS
FSOIL
GOTHAM GREEN PARTNERS
GVB BIOPHARMA
HARROD'S CREEK FARM
IGNITE DISTRIBUTION
JOY ORGANICS
KANNACO
KANNAWAY
LANDRACE BIOSCIENCE
M&C COMMUNICATIONS
NEW LEAF DATA SERVICES
OZ BOTANICALS
PANXCHANGE
PINNACLE HEMP
PRESENCE MARKETING
PRIORITY PAYMENT SYSTEMS
QUEEN CITY HEMP
SOZO HEMP
VERITAS FARMS
WE ARE FOR BETTER ALTERNATIVES

ADVOCACY PARTNERS*

ALLIANCE FOR NATURAL HEALTH USA
ASSOCIATION OF WESTERN HEMP PROFESSIONALS
AMERICANS FOR SAFE ACCESS
AMERICAN HERBAL PRODUCTS ASSOCIATION
CALIFORNIA HEMP COUNCIL
CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
COUNCIL FOR RESPONSIBLE NUTRITION
FRIENDS OF HEMP
HEMP ALLIANCE OF TENNESSEE
HEMP INDUSTRIES ASSOCIATION
iHEMP MICHIGAN
KENTUCKY HEMP ASSOCIATION
MIDWEST HEMP COUNCIL
MINORITY CANNABIS BUSINESS ASSOCIATION
NATIONAL CANNABIS INDUSTRY ASSOCIATION
REALM OF CARING
SPARTAN SWORD
TEXAS HEMP COALITION
UNITED NATURAL PRODUCTS ALLIANCE
U.S. HEMP BUILDING ASSOCIATION
VIRGINIA HEMP COALITION
VOTE HEMP
WE ARE FOR BETTER ALTERNATIVES
WHOLISTIC RESEARCH AND EDUCATION FOUNDATION
WISCONSIN HEMP ALLIANCE

**Advocacy partners do not necessarily endorse the positions of the US Hemp Roundtable.*

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