U.S. Hemp Roundtable

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VIA EMAIL

June 29, 2021

Ms. Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm 2438
Empire State Plaza
Albany, New York 12237
Via Email: REGSQNA@health.ny.gov

RE: Comments on Updated Proposed Regulations to Implement the New York State Cannabinoid Hemp Program

Dear Ms. Ceroalo:

The U.S. Hemp Roundtable appreciates the opportunity to provide the following comments on the New York State Department of Health's ("DOH") updated Proposed Regulations concerning the processing, manufacturing, and retail sale of cannabinoid hemp products ("the Proposed Regulations"). The Roundtable is the industry's leading national business advocacy organization that represents over 80 firms from across the country – at each link of the hemp supply and sales chain – and includes the ex officio membership of the industry's major grassroots organizations.

The Roundtable appreciates the DOH's thoughtful consideration of stakeholder comments, and its willingness to align the Proposed Regulations' labeling and testing requirements with existing federal and state requirements applicable to cannabinoid hemp products. We were especially pleased to see the DOH's incorporation of several of the Roundtable's comments from our December 2020 and January 2021 comment submissions. While the majority of requirements outlined in the updated Proposed Regulations are reasonable and workable for the industry, we offer the following recommendations to further improve upon the language and ensure it reflects sound science, as well as best practices that we believe are working well for the vast majority of the industry.

(1) Section 1005.9(a)(3)(ii), Disclosure of total tetrahydrocannabinol ("THC") on product packaging

Although we appreciate the DOH's revision to clarify that, for purposes of product labeling, only detectable levels of total Δ9-THC, Δ8-THC, and Δ10-THC must be disclosed, the Roundtable maintains that the Proposed Regulations should not mandate this disclosure unless these forms of THC are intentionally added to the product or called out in marketing. However, we also acknowledge the DOH's desire to provide consumers with additional information regarding total THC levels found in products. We again urge the DOH to limit disclosure to only total THC per serving, and to permit these amounts to be rounded.

This approach is more feasible for manufacturers while also providing consumers with adequate information regarding the total THC present in the product. Listing the total amount per container or package may encourage over-consumption of the product, or unnecessarily alarm consumers, especially in the case of multi-serving products such as dietary supplements that may contain a 60- or 90-day supply, whereby the total THC per package may imply the product provides significantly more total THC than intended on a per serving basis. In addition, currently there is no scientifically validated testing method to reliably quantify Δ10-THC, thereby making it difficult to accurately quantify the amount of Δ10-THC both per serving and per container. The AOAC INTERNATIONAL ("AOAC") Official Methods of Analysis ("OMA"), an international source of standards development and method validation drawn from the expertise of many contributing countries and organizations, has not yet reached a reliable method to quantitate Δ10-THC.

If the DOH intends to maintain the requirement to list total THC per serving and total THC per package or container, we request the department consider the approach adopted by Colorado, either by modifying the Proposed Regulations or through interpretative guidance, which will help ensure consistency in labeling across the states. In its labeling guidance for the hemp industry, the Colorado Department of Public Health and Environment ("CDPHE") provides the following as an acceptable statement for THC disclosure: "Container ≤ 15 mg Total THC Which ≤ 0.25 mg THC per serving."[1]

The impetus for this "≤" flexibility provided by CDPHE – which maintains truth and transparency in labeling – is due to the significant impact on all businesses, particularly small businesses, as it relates to label, carton, and labeling and packaging costs due to the frequency of label changes needed to address the inherent variability of naturally occurring levels of THC, in particular for hemp extract products. This approach would also help address the current lack of a reliable method to quantify Δ10-THC. Thus, we urge the DOH to implement and enforce this labeling requirement in a flexible and reasonable manner, if the manufacturer or distributor is complying with the spirit of the requirement. Please note "outer" is deleted in our suggested edits below, as this appears to be a typo.

(3) the number of servings per ~~outer~~ package or container, including the milligrams per serving ~~and the milligrams per package of~~:

(i) CBD;

(ii) "Total THC" or "THC" which for the purposes of product labeling shall include detectable levels of total Δ9-Tetrahydrocannabinol, Δ8-Tetrahydrocannabinol and Δ10- Tetrahydrocannabinol; and

(2) Section 1005.9(f)(2), THC warning requirement

We appreciate the DOH's revisions to clarify which cannabinoid hemp products must include a warning "that the product is derived from hemp and may contain THC which could result in a failed drug test." However, this provision would only exempt products made from "broad spectrum" hemp extract if the extract is "derived entirely from hemp grown, extracted, and manufactured in New York State." If a company is compliant with the definition of "broad spectrum" – which is mandated under Section 1005.8(e) – we see no reason why this exemption should be limited to New York-sourced hemp extract, and respectfully submit this restriction unfairly disadvantages out-of-state manufacturers. We strongly urge the DOH to modify the language as provided below.

[1] Colorado Department of Public Health and Environment, CBD LABELING GUIDELINES: Tinctures (April 2021), available at: https://drive.google.com/file/d/1HXfoIGIoeepJn2-neyQQEsxW-Tnmsq5M/view.

(2) that the product is derived from hemp and may contain THC which could result in a failed drug test. Provided however, this warning may be omitted for cannabinoid hemp products that are: topically applied; made exclusively using an "isolate;" or made from "broad spectrum" hemp extract ~~derived entirely from hemp grown, extracted, and manufactured in New York State~~;

(3) Section 1005.9(a)(3)(ii), Font requirements for certain label disclosures

We request this section include an exception in cases where the disclosure of marketed cannabinoids per serving occurs in the Supplement Facts panel. As noted in our previous comments, Section 403A of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") prohibits states from establishing requirements for nutrition labeling of food (including dietary supplements) that are not identical to federal requirements.[2] Requiring marketed cannabinoid disclosure to be in bold and in at least one font size larger than other required text, as required under this section, would be preempted if such disclosure occurs in the Supplement Facts panel, where many companies currently disclose this information. To require this as an additional disclosure outside of the Supplement Facts panel conflicts with federal law, is specifically prohibited under federal law, would be duplicative and thus both confusing and unhelpful to the consumer, and would result in a disadvantage to both the consumer and the business by unnecessarily taking up valuable label space, which is already severely limited due to the growing number of state labeling requirements for hemp products. We therefore request the following revision.

(g) No information required to be listed on cannabinoid hemp product labeling or packaging in accordance with this section shall be smaller than 4.5-point font, and the information required by subparagraphs (a)(3)(i) through (iii) and paragraph (f)(2) of this section shall be bolded and at least one font sized larger than other text required to be listed on the product label. This section does not apply to the information required under subparagraph (a)(3)(i) and (iii), provided however that such information is included in the Supplement Facts panel.

(4) Section 1005.21, Effective date for labeling requirements

If the DOH intends to proceed with the current labeling requirements as drafted, we ask that the effective date for labeling requirements be changed to one year from the adoption date of the regulations. Significant label changes such as those required under Section 1005.9 will require ample time for companies to not only produce new labels and re-label products, but to exhaust existing inventory. Notably, FDA typically provides companies with at least one year, if not longer, to implement label changes. Likewise, the California Office of Environmental Health Hazard Assessment, which administers the state's Proposition 65 Warning Regulations, provides an effective date of one year from the time a new warning requirement is adopted. We urge the DOH to follow these agencies and provide a one-year effective date for the labeling requirements.

Moreover, many companies are attempting to produce labels for cannabinoid hemp products that could be used across all states, in an effort to avoid creating state-by-state labels which is not only burdensome and cost-prohibitive, but also wasteful. Allowing additional time to transition to the Proposed Regulations' labeling requirements would be extremely helpful to emerging businesses and those impacted by the COVID-19 pandemic by reducing excessive costs and waste, as it avoids the need to re-label products that are already labeled and are very likely to be in New York retailers' inventory after the adoption date of the Proposed Regulations.

[2] *See* 21 USC 343-1. National uniform nutrition labeling.

(5) Section 1005.8(a)(11), Prohibition on cannabinoids created through isomerization

This section prohibits the use of "synthetic cannabinoids, or cannabinoids created through isomerization, including Δ8-tetrahydrocannabinol and Δ10-tetrahydrocannabinol." While the Roundtable agrees that Δ8-THC and Δ10-THC created through isomerization should not be sold as cannabinoid hemp products under the Proposed Regulations' framework due to the potential public health and safety risks, we have concerns that this prohibition may limit the ability to commercialize otherwise legal and non-intoxicating cannabinoids. For example, CBD-A can be converted into CBD through isomerization, and this section as written may restrict the sale of CBD produced through this process. As the science regarding minor cannabinoids continues to emerge, this language may also restrict the sale and development of these products, if produced through isomerization.

We urge the DOH to revise this section and limit its scope to forms of THC and THC isomers that are potentially intoxicating, as indicated below, which is also similar to the approach currently being considered by the Michigan legislature.[3]

> Section 1005.8(a)(11) – not contain synthetic cannabinoids, or ~~cannabinoids~~ tetrahydrocannabinols created through isomerization, including Δ8-tetrahydrocannabinol and Δ10-tetrahydrocannabinol and tetrahydrocannabinols that are structural, optical, or geometric isomers of tetrahydrocannabinols described in this section;

(6) Section 1005.10(i), Revisions to biological limits

Concerning the proposed biological limits, the limit for Salmonella does not include the sample amount, which is critical for testing accuracy and must also be balanced with cost factors. The Proposed Regulations provide for a 1-gram sample amount for Shiga toxin-producing Escherichia coli (STEC E. coli), which we believe is also sufficient for Salmonella. Although some manufacturers use a 10-gram sample, this larger size sample can have a significant economic impact on small businesses that produce dietary supplements. In addition, to ensure consistency with industry best practices, the limits for both E. coli and Salmonella should be expressed as "none detected," rather than "none present" in 1 gram.

1. Shiga toxin-producing Escherichia coli (STEC E. coli) and other pathogenic E. coli, none ~~present~~ detected in 1 gram
2. Salmonella, ~~none present~~ detected in 1 gram

(7) Section 1005.9(a)(1), Products intended for sublingual or oral absorption

The FD&C Act defines a "dietary supplement," in part, as a product that is "intended for ingestion."[4] Because sublingual products and products intended for "oral absorption" are intended to enter the body directly through the skin or mucosal tissues, they are not dietary supplements according to FDA, and the Agency has sent numerous Warning Letters to dietary supplement firms citing this prohibition.[5] In fact, dietary supplement companies have been warned by FDA for merely implying a sublingual, skin or mucosal tissue delivery instruction by using terms alternative to "sublingual," such as "place under your tongue" or "place on your tongue and hold for 10 seconds before swallowing." We therefore ask the following language be revised as indicated to align with federal law and avoid potential confusion among companies that may view the language as permitting the sale of sublingual or oral absorption products as dietary supplements. We have also suggested an additional but

[3] Michigan House Bill 4517, as passed by the House of Representatives, http://www.legislature.mi.gov/documents/2021-2022/billengrossed/House/pdf/2021-HEBH-4517.pdf.
[4] *See* 21 USC 321(ff)(2)(A)(i).
[5] *See*, e.g., FDA Warning Letter to DK Vitamins (Feb. 5, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/dk-vitamins-566205-02052019.

minor revision to further align with the FDA's regulations, as the language should reference a "nutrition or supplement facts panel."

(1) if the cannabinoid hemp product is consumed through ingestion, ~~including sublingual or oral absorption,~~ comply with the requirements in Title 21 Code of Federal Regulations Part 101 and include a nutrition~~al~~ or supplement facts panel that is based on the number of servings within the container;

* * *

In closing, the Roundtable once again expresses its appreciation for the opportunity to comment on the Proposed Regulations, which are among the most thoughtful and progressive in the country, and we respectfully urge the DOH to consider our recommendations outlined above to further improve upon the language.

Thank you for your consideration.

Sincerely,

Jonathan Miller
General Counsel
U.S. Hemp Roundtable

2021 U.S. HEMP ROUNDTABLE

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