U.S. Hemp Roundtable

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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 Proposed Regulations to Implement the New York State Cannabinoid Hemp Program

Dear Ms. Ceroalo:

The U.S. Hemp Roundtable appreciates the opportunity to comment on the New York State Department of Health's ("DOH") 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 applauds the DOH's effort to establish a robust, comprehensive framework for the regulation of cannabinoid hemp products. We believe that, as a whole, the Proposed Regulations strike an appropriate balance between ensuring consumer safety and maintaining consumer access to safe, high quality cannabinoid hemp products. We offer the following comments and recommended revisions to the Proposed Regulations to provide clarity and promote compliance within the industry, both at the federal and state level. In particular, we urge the DOH to consider aligning its Proposed Regulations wherever possible with 21 CFR Part 101, the FDA's labeling regulations for food and dietary supplements, and current industry best practices, such as those required under the U.S. Hemp Authority® Certification Program.[1] Doing so will help promote uniformity in labeling cannabinoid hemp products, thereby preventing consumer confusion while also reducing burdens on manufacturers and marketers seeking to comply with both state and national standards for the labeling of hemp food and supplement products, and ensure all information presented in labeling is truthful, accurate, and substantiated.

Our specific comments regarding the Proposed Regulations, along with recommended edits where appropriate, are outlined below.

[1] The U.S. Hemp Authority® Certification Program is the hemp industry's initiative to provide high standards, best practices, and self-regulation, giving consumers and retailers confidence in hemp and CBD products.

High Priority Issues:

- **Section 1005.1, Definitions.** We noted several definitions that we strongly believe should be revised to more closely align with the hemp industry's and consumers' understanding of these terms, as well as the practical implications of using these terms in labeling. Importantly, consumers may be confused by these state-specific definitions and companies using these terms in labeling may be exposed to potential liability, as these terms should accurately communicate to consumers what is in the product (and what is not).
    - Because it is difficult to entirely remove all Δ9-Tetrahydrocannabinol ("Δ9-THC") from a cannabinoid hemp product, the DOH should qualify the definition to make it clear that trace amounts defined as non-detectable may be present in "broad spectrum" products. In addition, the language should clarify that the definition applies to finished cannabinoid hemp products labeled as "broad spectrum" to accurately reflect how this term is being used, and to better align with the definition of "full spectrum."
        - "(a) *Broad spectrum* is a term used in finished product labeling and means ~~a concentrate extracted from hemp~~:
          (1) a cannabinoid hemp product containing multiple cannabinoids,
          (2) but where all Δ9-Tetrahydrocannabinol (THC) has been removed to non-detectable levels using a fit-for-purpose method with a limit of quantification of less than 0.01%.

    - To avoid consumer confusion, the definition of "cannabinoid hemp product" should be clarified to include *only* products that contain cannabinoids, while excluding products that are composed entirely of hemp grain and seed-derived products (such as hemp seed oil) or composed entirely of hemp terpenes, as these products may contain only trace amounts of cannabinoids. Further, FDA has not objected to the designation of certain hemp grain and seed-derived products as "Generally Recognized as Safe" ("GRAS"), as discussed below.
        - (d) *Cannabinoid hemp product* means hemp or any product manufactured or derived from hemp~~, including hemp-derived terpenes~~, in its final form, that are used for human consumption and contain more than trace levels of cannabinoids. Cannabinoid hemp product shall not include cosmetics or products that are composed entirely of hemp grain or hemp seed-derived ingredients.

    - The definition of "full spectrum" should be revised to better align with the industry's use of this term. To that end we recommend utilizing the U.S. Hemp Authority's definition of "full spectrum extract," taken from its Certification Program Guidance Procedures.[2]
        - (n) *Full spectrum* is a term used in finished product labeling and means:
          (1) a cannabinoid hemp product containing multiple hemp-derived cannabinoids ~~that is derived from a hemp extract~~;
          (2) includes THC and other cannabinoids, terpenes, and other naturally occurring compounds, that has been processed without intentional complete removal of any compounds, and has a final THC quantification of not greater than 0.3%; and ~~contains cannabinoids, aromatics, essential vitamins and minerals, fatty acids, protein, chlorophyll, flavonoids, or terpenes; and~~

[2] We also note that the U.S. Hemp Authority® Certification Program Guidance Procedures are subject to extensive stakeholder and public comment.

(3) where the multiple-hemp derived cannabinoids have not been formulated from the addition of multiple isolated cannabinoids ~~has not been reformulated or has not had cannabinoid isolates or distillates added to it~~.

- It is unclear why "hemp extract" has been defined to exclude food ingredients that are generally recognized as safe ("GRAS") under federal law.[3] Currently, FDA takes the position that CBD specifically cannot be added to food, but has not stated the same with respect to hemp extracts more broadly. In the future FDA may designate additional hemp-derived ingredients,[4] including hemp extract, as GRAS, and therefore the Proposed Regulations should not presumptively define "hemp extract" to exclude GRAS food ingredients. We also ask for clarification that addresses the DOH's ability to set a lower threshold for Δ9-THC, such that the concentration cannot be set at a level below 0.3%.
  - (p) *Hemp extract* means all derivatives, extracts, cannabinoids, isomers, acids, salts of isomers derived from hemp and used for human consumption, with a Δ9-Tetrahydrocannabinol concentration of not more than an amount determined by the department, provided the amount is not less than 0.3%. Hemp extract shall not include~~:~~
    ~~(1) any food, food ingredient or food additive that is generally recognized as safe pursuant to federal law; or~~
    ~~(2)~~ any extract derived from hemp that is not used for human consumption.

- **Section 1005.3, Application for Cannabinoid Hemp Retail License**.
  - **Subsection (b)(3)** should be revised to require applicants to include only the information that is presented on the label in applications for licensure. FDA does not require food or supplement labels to include the name of the manufacturer, or the state or country of manufacture, and allows the listing of the distributor or packer to appear on the label.[5] In some cases, the manufacturer's name is propriety and brand owners that use a contract manufacturer should not be forced to disclose this information to retailers that may sell a competing product, or in a manner where the information could be accessible through a public records request. Further, it creates an added and unnecessary burden on retailers while not providing any added consumer protection benefit. Allowing retail applicants to include the name and location of the manufacturer *or* the distributor or packer achieves the same purpose, while protecting brand owners' proprietary information and reducing burdens on retailers.
    - (3) the name of the manufacturer, packer, or distributor, or cannabinoid hemp processor, and state or country ~~of manufacture~~ where the manufacturer, packer, or distributor is located, for all cannabinoid hemp products the applicant intends to offer for sale;

[3] We also note that a food product itself is not eligible to deemed GRAS; only the individual ingredients of the food product.
[4] On December 20, 2018, the FDA completed its evaluation of three generally recognized as safe (GRAS) notices for hemp seed-derived food ingredients that were submitted by Fresh Hemp Foods, Ltd. The agency has no questions about Fresh Hemp Food's conclusion that the following ingredients are GRAS under their intended conditions of use: hulled hemp seed (GRN765), hemp seed protein powder (GRN771), and hemp seed oil (GRN778). See *FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food*, https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food.
[5] *See* 21 CFR 101.5. Food; name and place of business of manufacturer, packer, or distributor.

- **Section 1005.9, Packaging and labeling of cannabinoid hemp product requirements**. The DOH's Regulatory Impact Statement on page 55 of the Proposed Regulations indicates that "no relevant rules or legal requirements of the Federal and State governments duplicate, overlap or conflict with these proposed regulations." However, we noted several aspects of the labeling requirements that differ from or are duplicative of FDA-mandated labeling requirements, and in some cases are specific to New York State. This will likely result in consumer confusion and require companies to produce New York-specific labels, while adding to a growing patchwork of state-by-state labeling requirements for hemp products and serving no meaningful consumer protection purpose. More importantly, there are several aspects of the Proposed Regulations that clearly conflict with the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and its implementing regulations, in that the Proposed Regulations require information to appear in the nutrition label that is neither required nor permitted to appear under 21 CFR 101.9 or 21 CFR 101.36, which are the primary labeling regulations for food and dietary supplement nutrition labels, respectively.[6] The Proposed Regulations likewise conflict with the ingredient listing requirements in 21 CFR 101.4. Section 403A of the FD&C Act prohibits states from establishing requirements for nutrition labeling of food (including dietary supplements) that are not identical to federal requirements, and as a result these conflicting and differing requirements in the Proposed Regulations are preempted.[7]

[6] Of note, FDA regulates dietary supplements as a category of food, and therefore certain dietary supplement labeling requirements are covered under the general food labeling regulations. However, 21 CFR 101.36 governs nutrition labeling for dietary supplements specifically, i.e., the Supplement Facts panel.

[7] *See* 21 USC 343-1. National uniform nutrition labeling. (a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—
(1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title, except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title,
(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(c) of this title and that is applicable to maple syrup,
(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(h)(1) of this title and that is applicable to maple syrup,
(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 343(q)(5)(H)(ix) of this title, or
(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.
Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.
(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that—
(1) would not cause any food to be in violation of any applicable requirement under Federal law,
(2) would not unduly burden interstate commerce, and
(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a).

The Proposed Regulations should instead require compliance with the FDA's nutritional labeling requirements for food and dietary supplements under 21 CFR Part 101 and be revised as indicated below to address such conflicts. Otherwise hemp companies will be forced to violate well-established federal labeling rules in order to comply with New York law.

- **Subsection (a)** should mandate compliance with 21 CFR Part 101 to ensure that all cannabinoid hemp food and supplement products comply with federal labeling standards.
  - All cannabinoid hemp products distributed or offered for retail sale in New York State shall comply with 21 CFR Part 101 if marketed as a food or dietary supplement and include the following information on the product label or packaging:

- **Subsection (a)(1)(i)** requires a list of all ingredients in descending order of predominance by weight, including Δ9-THC concentration, CBD, and any other cannabinoids over 0.05%. Δ9-THC, CBD, and other cannabinoids are not ingredients (unless they are isolates added to the food or supplement), but rather naturally occurring constituents that are not permitted to be listed in the ingredients list under 21 CFR 101.4. Notably, FDA has issued Warning Letters to companies that have listed naturally occurring constituents in the ingredients list.[8] Therefore, this requirement conflicts with the FD&C Act and should be deleted, and instead the language should clarify that CBD and other cannabinoids must only be listed as an ingredient if added to the product in isolate form. The requirement to list *all* cannabinoids over 0.05% is also problematic because it is impossible to test for all of the cannabinoids – potentially hundreds – that may be in a hemp-based ingredient (in particular hemp extract ingredients) using the testing technology currently available. As a result companies will be forced to invest in new testing technology in order to disclose the minute, trace levels of every cannabinoid that may be present over 0.05% – which ultimately provides no consumer or public policy benefit. In addition, some companies may use proprietary varieties of hemp extract, whereby the ratios of various cannabinoids are confidential. A requirement to list ingredients in accordance with FDA labeling rules ensures that all intentionally added hemp ingredients, whether hemp extract or isolated cannabinoids, are included on the label in a manner that does not conflict with federal requirements.
  - (i) a list of all ingredients in descending order of predominance by weight in the product in accordance with 21 CFR Part 101, including but not limited to ~~total Δ9-Tetrahydrocannabinol concentration,~~ CBD and any other cannabinoids ~~over 0.05%~~ if added as isolated ingredients;

- Further to our comments above, **subsection (a)(1)(ii)** should be revised to delete the requirement that the nutrition label of cannabinoid hemp food products list "the amount of measurable cannabinoids in milligrams per serving and the total cannabinoid content of the package, and "[i]f applicable, the amount of total Δ9-Tetrahydrocannabinol in milligrams per serving and milligrams per package," as this conflicts with FDA's food labeling regulations. Under 21 CFR 101.9, only essential nutrients (e.g., Vitamin D, iron, calcium) and nutritional information such as calories, fat, sugar, etc. are required to be listed in the nutrition label. Requiring the listing of cannabinoids alongside these required elements conflicts with federal law and therefore should be deleted. If consumers or the DOH require additional information about the presence of cannabinoids in products, this

[8] *See*, e.g., FDA Warning Letter to Professional Botanicals, Inc. (Jul. 6, 2017), stating that "[n]aturally occurring constituents of an ingredient, such as the list of amino acids following pea protein isolate, are not considered ingredients and are not permitted in the ingredient list under 21 CFR 101.4," https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/professional-botanicals-inc-517911-07062017.

can be accessed through the certificate of analysis available via scannable bar code or QR code, as required under subsection 1005.9(a)(5) of the Proposed Regulations.

For dietary supplements, the language also conflicts with federal law and should be revised to require the declaration of cannabinoids per serving in accordance with 21 CFR 101.36, which outlines the specific requirements for declaring the serving size of dietary ingredients. For example, 21 CFR 101.36(b)(3)(iii) provides that constituents, such as naturally occurring cannabinoids, "*may be* listed" indented under the dietary ingredient and followed by their quantitative amount by weight per serving. Thus, if a cannabinoid isolate is not being added to a dietary supplement and a cannabinoid is not being called out on the label, to require its listing in the Supplement Facts panel conflicts with 21 CFR 101.36(b)(3)(iii). Rather than require the disclosure of "measurable" cannabinoids, which may not provide consumers with any meaningful information about the product, we urge the DOH to simply require the disclosure of "**marketed**" cannabinoids in accordance with 21 CFR Part 101, which companies selling cannabinoid hemp food and supplements should already be doing, and therefore directing companies to these FDA regulations also encourages compliance with federal law and promotes uniformity in labeling. However, if the DOH insists on mandating the disclosure of cannabinoids per serving or total cannabinoids per container, we request that the Proposed Regulations allow this disclosure to be provided via scannable bar code or QR code, as required under subsection 1005.9(a)(5). Doing so will preserve precious label space for companies that are faced with an increasing number of state-mandated requirements on top of existing federal labeling requirements.

Regarding the Δ9-THC requirement, like other naturally occurring hemp compounds, Δ9-THC is not intentionally added to products as an ingredient on its own; rather, companies using hemp-derived ingredients are calculating the concentration of Δ9-THC for purposes of compliance with federal and state 0.3% concentration limits. In addition, requiring companies to declare the total amount of Δ9-THC per serving or per package – whether in the nutrition label or elsewhere – may also encourage over-consumption of cannabinoid hemp products by drawing unnecessary attention to the Δ9-THC content. The disclosure of Δ9-THC is also not necessary because consumers seeking information about Δ9-THC (or other cannabinoid) content can obtain this information by accessing the certificate of analysis via the required scannable bar code or QR code on the label.

- (ii) the number of servings per package or container, including the amount of ~~measurable~~ marketed cannabinoids in milligrams per serving in accordance in 21 CFR Part 101 and which may be provided in the scannable bar code or QR code required under Section 1005.9. ~~and the total cannabinoid content of the package~~ ~~If applicable, the~~ ~~amount of total Δ9-Tetrahydrocannabinol in milligrams per serving and milligrams per package shall be stated on the label~~;

- **Subsection (a)(2)** should be revised to include "if applicable," as dietary supplements are not required under FDA regulations to include an expiration date.[9] This approach is also consistent with hemp product regulations

[9] "14. Must expiration dating be included on the label of dietary supplements? No. However, a firm may include this information if it is supported by valid data demonstrating that it is not false or misleading." *See* FDA, Dietary Supplement Labeling Guide:

in states such as West Virginia.[10] We also recommend additional flexibility to allow "best by" dating rather than expiration dating only, as some companies use "best by" dating for their cannabinoid hemp products.

- (2) an expiration or best by date, if applicable;

- Consistent with the FDA's requirements for food and dietary supplement labels,[11] **subsection (a)(4)** should be revised to allow either the name of the out of state manufacturer, *or* the name of the packer or distributor located out of state. As noted above, the name of the manufacturer is considered propriety for brand owners that use contract manufacturers, and providing the name of the packer or distributor provides sufficient means for the DOH to obtain any necessary information about the manufacturing of the product.
  - (4) the name of the cannabinoid hemp processor or out of state manufacturer, packer or distributor;

- **Subsection (a)(f)** should be revised to remove the 8-point font size requirement for warnings. Federal regulations provide no such requirement for warnings, including for mandatory warnings that must be used in food and supplement labeling.[12] In addition, the language already requires warnings to be "clear and conspicuous," which is more than adequate and flexible enough to accommodate different package and label sizes. Importantly, cannabinoid hemp products that are sold in small packaging could be forced to switch to larger packaging, which is not only wasteful but may have federal "slack-fill" implications.[13]
  - (f) All cannabinoid hemp products offered for retail sale shall include the following warnings on the product label or packaging, in a manner that is clear and conspicuous~~, and be written in text no smaller than size 8-point font~~:

- **Subsection (a)(f)(2)** should be deleted in its entirety, as no other state requires this type of THC warning for hemp-derived products, leading to yet another state-state specific requirement that will occupy shrinking label space. Further, it should be up to an individual company to determine whether such a warning is necessary based on its own THC testing, which may differ among companies, and the specific product being tested. The statement may also cause unnecessary alarm and confusion for consumers who may not understand the product contains only trace levels of THC in accordance with federal law. Alternatively, the DOH could require companies to link the scannable bar code or QR code required under subsection 1005.9(a)(5) to FAQs or information regarding the risks associated with hemp and drug testing.
  - (2) ~~a warning stating that the product is derived from hemp and may contain THC which could result in the consumer failing a drug test for marijuana~~;

- **Section 1005.10, Laboratory testing requirements for cannabinoid hemp.**
  - The Isopropyl Alcohol and Propane limits under **subsection (g), Residual Solvents** should be revised to permit 5,000 parts per million ("ppm"), as the current limits in the Proposed Regulations are stricter than what other

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Chapter I. General Dietary Supplement Labeling (April 2005), https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide-chapter-i-general-dietary-supplement-labeling#1-14.

[10] *See*, e.g., W. Va. Code R. §61-30-7.12h, requiring hemp products labels to include an "expiration or use by date, if applicable."

[11] *See* 21 CFR 101.5. Food; name and place of business of manufacturer, packer, or distributor.

[12] *See* 21 CFR 101.17. Food labeling warning, notice, and safe handling statements.

[13] In accordance with section 403(d) of the act, a food shall be deemed to be misbranded if its container is so made, formed, or filled as to be misleading. *See* 21 CFR 100.100.

states and national standards allow. For example, the California Bureau of Cannabis Control ("CBCC") sets a limit of 5,000 ppm for these solvents under its regulations for the cannabis industry.[14] Likewise, the U.S. Pharmacopeia ("USP") classifies Propane (listed as 1-Propanol and 2-Propanol) as Class 3 Residual Solvents, which USP considers to be "less toxic and of lower risk to human health than Class 1 and Class 2 residual solvents," and sets a limit of 5,000 ppm.[15]

- 4. Isopropyl Alcohol, ~~500~~ 5,000 parts per million.
  18. Propane, ~~2,100~~ 5,000 parts per million.

- The limits in **subsection (i), Biological Limits** should be revised to include a sample weight of 1 gram, as the determining factor is typically batch size and most state cannabis testing regulations specify 1 gram in their limits.[16]
  - 1. Shiga toxin-producing Escherichia coli (STEC E. coli) and other pathogenic E. coli, none ~~present~~ detected in 1 gram.
  - 2. Listeria monocytogenes, none ~~present~~ detected in 1 gram.
  - 3. Salmonella, none ~~present~~ detected in 1 gram.

- Under **subsection (j), Mycotoxin Limits** the limit for Ochratoxin should be specific to Ochtratoxin A, which is the most prevalent type.
  - 2. Ochratoxin A, 20 parts per billion.

- **Section 1005.11, Requirements for cannabinoid hemp retailers**.
  - **Subsection (d)** allowing the department to require retailers to display cannabinoid hemp products separately and out of the reach of children should be deleted. Display mandates create an undue burden on businesses, serve no meaningful public purpose, and send a harmful message thereby undermining the viability of the entire hemp market. In particular, dictating the manner and/or location of where these safe, legal, general wellness items must be displayed sends an inaccurate and inappropriate message to consumers: that these safe and legal wellness products are dangerous or should be associated with a vice of some sort. Many if not most retailers will choose not to carry cannabinoid hemp products if they are forced to display them separately, which will undermine industry diversity and inclusion, and threaten market sustainability overall.
    - (d) ~~The department may require cannabinoid hemp products to be kept separate from other products on display and out of the reach of children~~.

  - **Subsection (e)** also threatens the hemp market by forcing retailers to act as "regulators" of cannabinoid hemp products. Specifically, the requirement that retailers must maintain "the certificate of analysis *and* evidence that cannabinoid hemp products meet all of the requirements of this Part" for cannabinoid hemp products purchased from an out of state manufacturer places an additional and unnecessary burden on retailers to

[14] 16 CCR § 5718. Residual Solvents and Processing Chemicals Testing, https://bcc.ca.gov/law_regs/cannabis_order_of_adoption.pdf.
[15] USP Chapter 467, Residual Solvents, https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf. USP does not set a limit for Isopropyl Alcohol.
[16] *See*, e.g., 16 CCR § 5720. Microbial Impurities Testing, https://bcc.ca.gov/law_regs/cannabis_order_of_adoption.pdf.

confirm compliance for every such product in their inventory. Subsection 1005.16(c) of the Proposed Regulations already prohibits retailers from selling any cannabinoid hemp product that fails to meet the standards and requirements of Sections 1005.8, 1005.9 and 1005.10, so we see no reason why additional recordkeeping requirements should be imposed based on where a product is manufactured. Even with the various revisions recommended in our comments, the Proposed Regulations together with federal regulations provide more than adequate requirements to ensure cannabinoid hemp products are properly manufactured, tested, and labeled. This language may also discourage retailers from carrying out of state products due these added burdens, which would negatively impact the viability of the hemp market as a whole.

- (e) Cannabinoid hemp retailers shall maintain sufficient records of where cannabinoid hemp products were purchased from, including the name of the cannabinoid hemp processor if applicable, and the wholesaler or permitted distributor if applicable. ~~Where cannabinoid hemp products are purchased from an out-of-state manufacturer, the cannabinoid hemp retailer shall also maintain the name, address, certificate of analysis and evidence that cannabinoid hemp products meet all of the requirements of this Part.~~

- **Effective Date of the Regulation**. The Summary and Compliance Schedule indicate that the Proposed Regulations will be become effective upon filing of notice of adoption with the Secretary of State. We strongly urge the DOH to permit retailers to continue to sell cannabinoid hemp products that are part of their existing inventory prior to the effective date of the Proposed Regulations, and include a minimum 180-day effective date for the Proposed Regulations to allow ample time for the hemp industry to come into compliance with the regulations, especially in light of the potentially significant label changes provided in the proposal.

Additional Priority Issues:

- **Section 1005.1, Definitions**. We also request the DOH make the following additional revisions to certain definitions in the Proposed Regulations to better align with consumer expectations and industry best practices.
  - The definition of "cannabinoid hemp processor" should be clarified to state that only entities that extract hemp or manufacture cannabinoid hemp products *and* are located in New York State must obtain a license. As written, the definition could be understood to require out of state extractors and manufacturers to obtain a department-issued license.
    - (f) *Cannabinoid hemp processor* means a person licensed by the department to extract hemp extract and/or manufacture cannabinoid hemp products in the State of New York, whether in intermediate or final form, to be used for human consumption.

  - The definition of "distillate" should be revised because as written, it may be understood to prohibit even unintentional, trace amounts of impurities that are unlikely to pose harm. Even if a company takes all appropriate steps to purify an ingredient, it is difficult if not impossible to ensure that absolutely all amounts of impurities have been removed. Trace amounts may still be unintentionally introduced into a product during the supply chain due to shared equipment, packaging, and similar issues. Further, these trace amounts are highly unlikely to pose risks to consumers.
    - (j) *Distillate* means a concentrate where a segment of cannabinoids from an initial extraction are selectively concentrated through heating and cooling, with ~~all~~ impurities removed.

- To avoid confusion, the definition of "used for human consumption" should clarify that the term refers to "ingestion," as "consumption" is typically not used in reference to products that are topically applied to the body, such as cosmetics.
    - (x) *Used for human consumption* means intended by the manufacturer or distributor to be~~: (1)~~ used for ingestion by humans ~~consumption~~ for its cannabinoid content~~; or (2) used in, on or by the human body for its cannabinoid content~~.

- **Section 1005.8, Cannabinoid hemp product requirements.**
    - **Subsection (a)(2)** should be removed, or at least modified to include a notice-and-comment rulemaking requirement, regarding the department's ability to impose a cap on total Δ9-THC. The cap chosen by the department could have a significant impact on the hemp marketplace and require otherwise legal cannabinoid hemp products to be reformulated. We are not aware that the Δ9-THC content of cannabinoid hemp products that meet the 0.3% limit for Δ9-THC concentration are being misused for their Δ9-THC content, or pose serious health risks to consumers. Further, consumers are not seeking out hemp food and dietary supplements for their THC content – especially given the continued legalization and decriminalization of adult use, high THC cannabis products.
        - (2) contain no more than three-tenths of a percent (0.3%) total Δ9-Tetrahydrocannabinol concentration. ~~The department shall have the ability to impose a total Δ9-Tetrahydrocannabinol cap in milligrams per serving and milligrams per package for cannabinoid hemp products based on the product form, volume, number of servings, and ratio of CBD to THC~~;

    - **Subsection (a)(6)** should be revised to allow for more flexibility in terms of test results for concentration of total cannabinoid content. Because cannabinoids are naturally occurring constituents of the hemp plant and levels can vary depending the hemp strain from which the cannabinoids are derived, as well as weather, soil conditions, and other factors, the current 90% and 110% requirement for concentration of total cannabinoid content will pose challenges for many companies in the industry, especially those that utilize hemp extract as a source of cannabinoids rather than isolated cannabinoids. Notably, West Virginia's Hemp Products Rule permits labels to have an overage or underage of 20% of the amount declared on the label,[17] which is a reasonable and flexible approach given the natural variability of hemp-derived ingredients. In addition, FDA also permits certain naturally occurring nutrients to be present at 80% or more or 120% or less of the value declared in the nutrition label.[18] We therefore ask the DOH to take a similar approach to total cannabinoid content label claims.
        - (6) accurately reflect testing results and not contain less than ~~90~~ 80 percent or more than ~~110~~ 120 percent of the concentration of total cannabinoid content as listed on the product label;

[17] Labels will be considered misbranded when a WVDA analysis finds the claim is above or below 20% of the amount declared on the label. W. Va. Code R. §61-30-7.10.
[18] FDA, *Guidance for Industry: Guide for Developing and Using Data Bases for Nutrition Labeling* (March 1998), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-developing-and-using-data-bases-nutrition-labeling.

- While we applaud the DOH's efforts to establish a reasonable limit for total cannabinoids in food, beverage, and dietary supplements in **subsection (b)**, we have concerns that the 3,000 milligram per product cap for dietary supplements may be too low for some multiple serving tinctures, whereby the hemp extract and CBD is often concentrated. For example, if a tincture supplement provides 60 mg of total cannabinoids per serving, under the Proposed Regulations a product that provides a total of 60 servings (at 60 mg per serving) would be prohibited. Therefore we request that the total per product cap for cannabinoids in dietary supplements be increased to 3,500 milligrams in subsection (b). We also recommend that the DOH clarify that the per product limit for supplements applies to multi-serving products only, to avoid instances where a product contains 3,500 mg of cannabinoids but is recommended to be consumed in one serving.
    - (b) If the cannabinoid hemp product is a food or beverage manufactured under Part 117 of Title 21 Code of Federal Regulations, it shall not contain more than 25 milligrams of total cannabinoids per product. If the cannabinoid hemp product is a supplement manufactured under Part 111 of Title 21 Code of Federal Regulations, it shall not contain more than ~~3,000~~ 3,500 milligram of total cannabinoids per product, provided the product is a multi-serving product.

- **Subsection (c)** should be revised to clarify that pre-measured, multiple serving products such as capsules do not need to include a measuring device. Although we do not believe this was the intent of the Proposed Regulations, it would be helpful to expressly exclude these products from this requirement.
    - (c) If the cannabinoid hemp product contains multiple servings which are not individually wrapped or premeasured in the form of capsules, tablets, or a similar product format, it shall include a measuring device such as a measuring cap, cup or dropper with the product packaging. Hash marks on the package shall not qualify as a measuring device.

- **Section 1005.9, Packaging and labeling of cannabinoid hemp product requirements.**
    - **Subsection (a)(6)** should be deleted to remove the requirement that the state(s) or country (or countries) of origin be declared on the label. Currently only two states require similar but slightly different geographic sourcing information to be declared on labels,[19] and therefore this requirement will result in another state-specific labeling mandate, forcing companies to create new labels specifically for products sold in New York State without serving any clear public policy purpose. Alternatively, we request this information be provided through the required scannable bar or QR code under subsection 1009.5(a)(5) as suggested below.

      In addition, the bar code or QR code requirement should be clarified to permit the code to link to a website where a downloadable certificate of analysis may be obtained.

        - (5) a scannable bar code or QR code linked to a downloadable certificate of analysis, or linked to a website where the certificate of analysis can be downloaded and that provides;
        - ~~(6)~~ the state(s) of origin from which hemp used in the product was sourced or, if sourced from outside of the United States, the country (or countries) of origin;

[19] Alaska requires "[t]he industrial hemp pilot program or authorized international industrial hemp source from which the hemp originated" and Oklahoma requires "[t]he country of origin of the cannabidiol." *See* 11 AAC 40.420 and Okla. Stat. tit. 63, § 1-1431.

If the DOH insists on requiring the origin of the hemp on the product label itself, we urge that it be limited to country of origin only, rather than the state *or* country of origin.

- ~~(6)~~ the ~~state(s)~~ country (or countries) of origin from which hemp used in the product was sourced ~~or~~, ~~if sourced from outside of the United States, the country (or countries) of origin~~;

- **Subsection (b)** should be revised to provide additional clarity as to what type of packaging would be considered "attractive to anyone under 18 years of age."
  - (b) No cannabinoid hemp product shall be packaged or contained in such a manner so as to be attractive to anyone under 18 years of age [including no cartoons or images popularly used to advertise to children, or the imitation of a candy label]…

- **Subsection (f)(3)** should be deleted or revised as suggested below, as currently Colorado is the only other state to require this warning, creating yet another state-specific requirement that will also occupy precious label space, without providing a meaningful benefit. In addition, many dietary supplements already include a similar label statement in accordance with 21 CFR 101.93, which requires all dietary supplements that bear structure/function claims to include the following statements in labeling: "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." or "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[20] Therefore the proposed warning is duplicative and unnecessary for cannabinoid hemp dietary supplement products. We also believe it is wholly unnecessary for cannabinoid hemp food products, as federal labeling regulations require no such warnings for foods and we are not aware of evidence suggesting that consumers believe these products are in fact evaluated by the FDA for safety and efficacy. If the DOH believes this warning statement is necessary, we ask that it be limited only to dietary supplement labels that do not already include the federal disclaimer noted above.
  - "(3) that the product, if labeled as a dietary supplement, has not been evaluated by the Food and Drug Administration for safety or efficacy, unless the label includes the disclaimer statements required under 21 CFR 101.93;

- **Subsections (f)(1) and (4)** should be combined to streamline the required label language for sensitive populations, and to allow flexibility to accommodate language that is currently being used on product labels and achieves the same purpose – while also allowing some companies to maintain current labeling and save label space.
  - (1) ~~keep out of reach of children~~
    …
    (4) a statement indicating that the product is not intended for children or for those who are pregnant or nursing, and that the product should be kept out of reach of children ~~to consult their healthcare provider before use~~; and

- **Section 1005.10, Laboratory testing requirements for cannabinoid hemp.**

[20] *See* 21 CFR 101.93(c) and (d).

- **Subsection (1)** should be deleted, as it appears to require testing for a pathogen, toxicant, residual solvent, metal, or pesticide in cases where testing may not be available, and therefore a company has no way of identifying that the contaminant even exists. Further, the broad, ambiguous prohibition on "levels of any" such contaminant would mean that even trace amounts that pose no safety risk would suddenly adulterate a product. Whether a product is adulterated by the presence of a pathogen, toxicant, residual solvent, metal, or pesticide should only be based on sound science and a regulation that specifically delineates those pathogens, toxicants, residual solvents, metals, or pesticides and the acceptable level, which the DOH can achieve through future amendments to the Proposed Regulations.
    - (I) ~~If a cannabinoid hemp product is found to contain levels of any pathogen, toxicant, residual solvent, metal, or pesticide not enumerated in this section or by New York State law, then the product shall be considered adulterated and shall not be sold in New York State and shall be destroyed in accordance with 1005.7(d).~~

- **Section 1005.17, Penalties.**
    - **Subsection (b)(1)** imposes a fine of up to $1,000 for a first violation involving failure to comply with the Proposed Regulations, which is excessive for a first-time violation especially in cases where the violation may be minor, for example, failure to include a required label statement. Instead, we suggest lowering the fine to the more reasonable amount of $250, and adjusting second and third violations accordingly. In addition, given supply chain realities it is possible that products that are not labeled in compliance with the Proposed Regulations but are otherwise safe may still be on product shelves after the effective date, and $1,000 fine seems particularly excessive in such cases.
        - (i) a fine of up to ~~$1,000~~ $250 for a first violation;
          (ii) a fine up to ~~$5,000~~ $1,000 for a second violation within three-years; or
          (iii) a fine up to ~~$10,000~~ $5,000 for a third violation and each subsequent violation thereafter, within a three-year period.

* * *

In closing, we appreciate the opportunity to comment on the Proposed Regulations, and respectfully urge the DOH to include the suggested modifications described above, which we believe will encourage compliance and protect both consumers and the industry.

Thank you for your consideration.

Sincerely,

Jonathan Miller
General Counsel
U.S. Hemp Roundtable

2020 U.S. HEMP ROUNDTABLE

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