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

The Council for Responsible Nutrition (CRN)[1] submits the following comments to the New York State Department of Health (the Department), along with our attached position paper: *Hemp-Derived CBD Dietary Supplement Position* in response to the Proposed Regulation to implement the New York State Cannabinoid Hemp Program. Our position paper details CRN's support for a federal regulatory scheme enacted for hemp-derived CBD dietary supplements, and while we await clarity at the federal level for the application of federal requirements for dietary supplements to CBD, the promotion of state laws and regulations regulating hemp-derived CBD dietary supplements in a manner consistent with federal requirements for all dietary supplement products.

CRN continues to work with Congress to support federal legislation (previously introduced as H.R. 8179, the Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020.) This legislation directs that CBD be recognized as a lawful dietary ingredient to be regulated by the Food and Drug Administration (FDA), irrespective of any other definitional hurdles in the federal Food, Drug & Cosmetic Act, and will require that hemp-derived CBD products adhere to the same legal requirements for manufacturing, labeling, promotion and usage as any other dietary supplement. The legislation provides a clear legal pathway to market for dietary supplements containing hemp-derived CBD and will help protect the health and safety of consumers by addressing many of the concerns that currently exist from an untamed market. We expect Congress to consider legislation addressing this critical issue early in the 117th session and strongly encourage states looking to adopt their own hemp-related regulatory structures to fashion ones that would be consistent with that federal framework. In anticipation of

[1]The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 190+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit, www.crnusa.org. Follow us on: Twitter @CRN_Supplements, Facebook, and LinkedIn.

Congress's rapid consideration and enactment of this legislation, we encourage the following edits to the proposed New York regulation.

Section 1005.1 Definitions

Proposed Revisions: (a) Broad spectrum means ~~a concentrate extracted~~ an extract from hemp containing multiple cannabinoids, but where all Δ9-Tetrahydrocannabinol (THC) has been removed to non-detectable levels to be in compliance with the United States Department of Agriculture 0.3% THC limit for raw flower and finished product.

Rationale: CRN offers these revisions for better clarity for industry and consumer understanding of this term. Moreover, it is difficult to remove all THC from a cannabinoid hemp product and the Agriculture Improvement Act of 2018, (commonly referred to as the 2018 Farm Bill[2]) defines "hemp" as, "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 ("Δ9") tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."[3] Therefore, cannabinoid hemp product within the 0.3% THC threshold should be permitted, as applicable to THC levels.

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 commonly used by industry and understood by consumers.

Proposed Revisions: (d) Cannabinoid hemp product means hemp or any product ~~manufactured or derived from hemp, including hemp derived terpenes,~~ containing ingredients derived from hemp, including any intermediate material that may be included in a product that includes hemp or any hemp derivatives in its final form, that are used for human consumption. Cannabinoid hemp product shall not include cosmetics, products derived from hemp seed, or other hemp derivatives containing only trace levels of cannabinoids.

Rationale: CRN offers these revisions for clarification of the inclusion of all ingredients that are derived from hemp and that the definition of cannabinoid hemp product also include intermediate material in the product for regulation under this proposed rule. Moreover, hemp seed derived products can be legally marketed, provided they comply with federal Food, Drug and Cosmetic Act requirements.

[2] *See,* Agriculture Improvement Act of 2018, Pub. L. 115-334.
[3] *See,* Sec.297A. Definitions, (1) "Hemp", Pub. L. 115-334.

Proposed Revisions: (e) Cannabinoid hemp retailer means a person licensed by the department to sell cannabinoid hemp products, whether in intermediate or final form; ~~including via the internet~~, to consumers in New York State.

Rationale: CRN offers these revisions for clarification and uniformity with CRN's proposed revisions above to include "intermediate" materials and products in "final form". Additionally, CRN seeks further clarification from the Department. Specifically, as this definition is currently written - any company selling cannabinoid hemp products that are accessible to New York consumers online would need a license or a permit, per "Section 1005.14 (h) No person shall distribute cannabinoid hemp products manufactured out of state, to a cannabinoid hemp retailer within New York State, unless permitted pursuant to section 1005.18 of this Part." However, the requirements for licensure or permitting are not very clear for businesses that might fall into this category. For example, how might an out-of-state retailer with an online store determine the cost per facility or display the license in a conspicuous location? Moreover, including internet sales functionally creates an impossibility for a retailers' website to comply with the requirements of multiple states with varied regulations, and consequently, if ascertainable, increases consumer confusion. CRN requests that these requirements be further clarified for out-of-state companies who sell cannabinoid hemp products online to consumers in New York State.

Proposed Revisions: (j) Distillate means a concentrate where a segment of cannabinoids from an initial extraction are selectively concentrated through ~~heating and cooling~~ heating, evaporation and condensation, with virtually all impurities removed.

Rationale: CRN offers these revisions for the inclusion of current impurity extraction practices.

Proposed Revisions: (k) Distribute means to offer or sell cannabinoid hemp products to a cannabinoid hemp retailer, for retail sale to consumers taking delivery within New York state.

Rationale: CRN offers this revision for the clarification of the state's jurisdiction over consumers in the state and distribution activities taking place in the state.

Proposed Revisions: (l) ~~Extract or~~ Extraction means the process of concentrating, distilling, ~~or~~ isolating or using other techniques ~~one or more~~ to derive cannabinoids and other plant components from hemp or cannabinoid hemp.

Rationale: CRN offers these revisions for the inclusion of current processing practices.

Proposed Revisions: (m) ~~Flower product~~ Hemp raw material means any form of cannabinoid hemp product consisting of the flower, buds, leaves, roots or stems of the hemp plant, including trimmings thereof, intended for retail sale to consumers without further processing.

Rationale: CRN offers these revisions for better clarity for industry and consumer understanding of this term. However, alternatively, we would like to propose a complete strikethrough to this definition as falling under the purview of this statute, as parts of the hemp plant that were not on the controlled substances list, prior to the 2018 Farm Bill, like stalks, stems, and roots may not fall under the jurisdiction of the Department.

Proposed Revisions: (n) Full spectrum means a cannabinoid hemp product that ~~is~~:

(1) contains ingredients derived from a hemp extract;

(2) includes THC and other cannabinoids, terpenes, and other naturally occurring compounds, that has been processed without intentional removal of any compounds, and has a final THC quantification of not greater than 0.3% concentration; ~~contains cannabinoids, aromatics, essential vitamins and minerals, fatty acids, protein, chlorophyll, flavonoids, or terpenes~~; and

(3) may be fortified with exogenous botanical constituents such as cannabinoid or terpene isolates or distillates (if such fortification is disclosed in product labeling), ~~has not been reformulated or has not had cannabinoid isolates or distillates added to it.~~

Rationale: CRN offers these revisions to better align with the industry's use of this term.

Proposed Revisions: (o) Hemp means the plant Cannabis sativa L. and any part of such plant, including the roots and seeds thereof and all ~~derivates~~ derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a Δ9-Tetrahydrocannabinol concentration of not more than three tenths of a percent on a dry weight basis.

Rationale: CRN offers these revisions to include "roots" derived from hemp and a correction of a presumed typo.

Proposed Revisions: (p) Hemp extract means ~~all~~ any derivative~~s~~, extract~~s~~, cannabinoid~~s~~, isomer~~s~~, acid~~s~~, salt~~s~~ of isomer~~s~~ 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% on a dry weight basis. Hemp extract shall not include:

Rationale: CRN offers these revisions for better clarification of the inclusivity of "any" ingredient derived from hemp. CRN has also offered the inclusion of, "provided the amount is not less than 0.3%" so that this proposed definition would be in conformity with the THC threshold established in the 2018 Farm Bill's definition of "hemp".[4] Furthermore, without this inclusion, the Department could set a threshold limit of THC possibly less than 0.3%,

[4] *See,* Agriculture Improvement Act of 2018, Pub. L. 115-334.

which would not align with the current federal definition and further the patchwork of state regulation of hemp-derived CBD products.

Proposed Revisions: (t) New York Hemp Product means a cannabinoid hemp product that is derived from hemp exclusively grown, extracted and manufactured in New York, in compliance with section 1005.13 of this Part. Hemp seed originating outside of the state, but grown, extracted and manufactured in New York can be New York Hemp Product.

Rationale: CRN offers this revision for clarification that the Department intends to allow hemp product that is grown, extracted and manufactured in New York, but has utilized "seed" that has originated in another state or country to be allowed classification as "New York Hemp Product" should it meet the requirements set out above and in section 1005.13 of this proposed regulation.

Proposed Revisions: (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.~~

Rationale: CRN offers these revisions for better clarification of the Departments intent for this definition.

Section 1005.2 Application for cannabinoid hemp processor license.

Proposed Revisions: (b)(2) identification of ~~all real~~ property~~, buildings and~~ or facilities that are ~~will be~~ used in the extracting or manufacturing of cannabinoid hemp;

Rationale: CRN offers these revisions for clarification of the intent of the Department to require transparency to consumers while protecting proprietary information of businesses operating in the state.

Proposed Revisions: (b)(3) ~~the days and hours of operation~~ administrative operations;

Rationale: CRN offers these revisions to better align with the information the Department intends to solicit from a potential licensee.

Proposed Revisions: (c) Applications under this section shall be accompanied by a non-refundable application fee of ~~$1,000 for extraction and manufacturing~~ $500 for extraction and $500 for manufacturing. ~~, and $500 for a license to manufacture only.~~

Rationale: CRN offers these revisions for clarification and fairness should a licensee request a license solely for extraction or for manufacturing.

Section 1005.8 Cannabinoid hemp product requirements

Proposed Revisions: (a)(9) ~~be shelf stable; and~~

Rationale: CRN offers these revisions because CRN believes the Department's intent is to ensure cannabinoid hemp products meet federal good manufacturing practices (GMP) to ensure dietary supplements meet their label claims for identity, strength, purity and composition.[5] The term "shelf stable" is not a GMP term, however the concept of meeting label claims for the shelf life of the product is covered in 21 CFR 111.

Proposed Revisions: (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 finished 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 milligram of total cannabinoids per finished product.~~

Rationale: CRN offers these revisions for clarification of the Department's intent to regulate "finished product". CRN is not aware of evidence of 25 milligrams or 3,000 milligrams being demonstrable upper safe limits for cannabinoids, particularly as cannabinoids vary in effectiveness and we are open to discussing these proposed limits further with the Department. Other international regulatory authorities, such as Australia and Great Britain, have, for example, approved much larger daily servings. Further, if the intent of the 3,000 milligram limit is to restrict the total CBD content of a container (i.e., assuming a 25 mg dosage, no more than 120 servings per container) New York should provide some justification for this limit and why such limit is likely to deter intentional abuse through purchasing multiple containers.

Section 1005.9 Packaging and labeling of cannabinoid hemp products.

Proposed Revisions: (a)(1)(i) a list of all ingredients in accordance with Title 21 CFR 101.4 and in descending order of predominance by weight in the product, including but not limited to total Δ9-Tetrahydrocannabinol concentration, CBD and any other cannabinoid~~s~~ isolates over 0.05%; and

Rationale: CRN offers these revisions for clarification and consistency with current federal law. Δ9-THC, CBD, and other cannabinoids are not, "ingredients" unless they are isolates added to food or a supplement. Therefore, this proposed requirement conflicts with the federal

[5] *See,* 21 USC §342(g), *See,* 21 CFR Part 111.

Food, Drug and Cosmetic Act because Δ9-THC, CBD, and other cannabinoids that are not isolates, but rather naturally occurring, are not permitted to be listed in the ingredients list under 21 CFR 101.4. CRN proposes the inclusion of, "in accordance with Title 21 CFR 101.4" and the designation, "isolates" to clarify that Δ9-THC, CBD, and other cannabinoids must only be listed as an ingredient if added to the product in isolate form.

Moreover, the requirement to list all cannabinoids over 0.05% is also problematic because it is currently 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. Additionally, 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.

Proposed Revisions: (a)(1)(ii) the number of servings per package or container, including the amount of ~~measurable~~ marketed cannabinoids in milligrams per serving in accordance with 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;~~

Rationale: CRN offers these revisions for clarification and consistency with current federal law. The proposed language conflicts with federal law as related to the specific requirements for declaring the serving size of dietary ingredients under 21 CFR 101.36. If a cannabinoid isolate is not being added to a dietary supplement and a cannabinoid is not being called out on the label, for this proposed regulation to require its listing in the Supplement Facts panel conflicts with 21 CFR 101.36(b)(3)(iii). Requiring the disclosure of "marketed" cannabinoids in accordance with 21 CFR Part 101, not the disclosure of "measurable" cannabinoids, creates state regulatory consistency with federal law and promotes uniformity in labeling requirements.

Δ9-THC is also a naturally occurring hemp compound that 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. Moreover, 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.

Proposed Revisions: (a)(2) an expiration or best by date, if applicable;

Rationale: CRN offers these revisions for clarification and consistency with current federal law. CRN offers the use of "or best by" dating because some companies utilize this type of

designation. Moreover, under FDA regulations, dietary supplements are not required to include an expiration date, and therefore CRN has offered "if applicable" revision language.[6]

Proposed Revisions: (a)(4) the name of the cannabinoid hemp processor or out of state manufacturer, packer or distributor;

Rationale: CRN offers this revision for clarification and consistency with current federal law. The name of the manufacturer is considered propriety for brand owners that use contract manufacturers, therefore offering the options of providing the name of the "packer or distributor" provides any necessary information about the manufacturing of the product.[7]

Proposed Revisions: (a)(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:~~

Rationale: CRN offers this revision for clarification and consistency with current federal law. CRN offers the above strikethrough because federal regulations do not require text font size requirements for warnings, including mandatory warnings, that must be used in supplement labeling.[8] Moreover, the proposed, "clear and conspicuous" requirement is practical enough to accommodate different package and label sizes.

Proposed Revisions: (a)(f)(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;~~

Rationale: CRN offers this revision for practicality of spacing on dietary supplement packaging. This proposed warning statement will take up already dedicated label space and be a state-specific labeling requirement, that is currently not required in other states, that will contribute to the patchwork of state regulation of hemp-derived CBD products.

Section 1005.10 Laboratory testing requirements for cannabinoid hemp

Proposed Revisions: (g) Residual Solvent Limits.

Rationale: CRN would like to encourage the Department to consult with FDA regarding the use of solvents in dietary supplement processing and list limits that are not in conjunction with the marijuana industry, but rather USDA hemp regulation and FDA anticipated hemp-derived CBD regulation.

[6] *See*, Dietary Supplement Labeling Guide: Chapter I. General Dietary Supplement Labeling.
[7] *See*, 21 CFR 101.5.
[8] *See,* 21 CFR 101.17.

Section 1005.11 Requirements for cannabinoid hemp retailers

Proposed Revisions: (d) ~~The department may require cannabinoid hemp products to be kept separate from other products on display and out of the reach of children.~~

Rationale: CRN offers this revision with the contentions that should the Department require retailers separate cannabinoid hemp products, the Department will be placing an undue burden on retailers without adequate justification, while also promoting a stigma on these products in its required separation. Moreover, there are many products, if taken incorrectly could cause harm to children, that children have access to in stores that do not have limited accessibility requirements.

Proposed Revisions: (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.~~

Rationale: CRN offers this revision to express our concerns with forcing retailers to act as regulators of cannabinoid hemp products by confirming product compliance for every product of this type in their inventory.

Section 1005.13 New York Hemp Product

Proposed Revisions: (b) New York Hemp Product is a cannabinoid hemp product exclusively grown, extracted and manufactured in New York State and processed in New York State by processors licensed under this Part, who demonstrate compliance with all requirements enumerated by the department;

Rationale: The inclusion of “extracted and manufactured” keeps this provision consistent with the Department’s definition of “New York Hemp Product” and reflects the intent of CRN’s proposed clarification in that a hemp product can be classified as a New York Hemp Product, if the product is grown, extracted and manufactured in New York State, but with seeds from another state or country.

Section 1005.14 General prohibitions

Additional Revision Requests:

- References to "cannabinoid hemp" should be consistent with the Departments intent to regulate hemp (the plant) and hemp products that contain cannabidiol to conform to how the Department is intending to regulate hemp-derived cannabidiol and the THC limits that are included in those

products. Moreover, “industrial hemp” conforms to the 2018 Farm Bill and United States Department of Agriculture rules.

- **Effective Date of this Regulation.** CRN encourages the Department 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 Regulation.

Should you have any further questions about our position or CRN’s efforts at the federal level with respect to hemp-derived CBD, please do not hesitate to contact me. Thank you for your time and consideration.

Sincerely,

Amanda Darlington,
Director, Government Relations
Council for Responsible Nutrition