



October 16, 2024

Brenda Noble
Florida Department of Agriculture and Consumer Services
Division of Food Safety
Florida Capitol
Tallahassee, Florida 32399-0800
E-mail: Brenda.Noble@fdacs.gov

Re: Written Comments & Request for Hearing – 5K-4.034 Hemp Extract for Human Consumption

Dear Ms. Noble:

The U.S. Hemp Roundtable sincerely appreciates the efforts undertaken by the Florida Department of Agriculture and Consumer Services (“Department”) in developing Proposed Rule 5K-4.034 Hemp Extract for Human Consumption (“Proposed Rule”) to implement Senate Bill 1676, which became law in 2023. To be clear, we agree with and support Senate Bill 1676’s goal of regulating ingestible and inhalable hemp extract products so that they are not attractive to children, as does the majority of the hemp industry. However, the Proposed Rule will effectuate major changes that will hurt hemp businesses in Florida, cause confusion and disruption in interstate commercial markets, and increase compliance costs.

I. 5K-4.034(5)(i) & (5)(j) – Exception for hemp gummies and hemp beverages

In general, sections (5)(i) and (5)(j) prohibit color additives and other substances when used as a color additive in hemp or consumable hemp extract products. The Proposed Rule does not contain any exception. We recommend that an exception for added for color additives in hemp gummies and hemp beverages.

First, the U.S. Food and Drug Administration (“FDA”) permits the use of color additives in beverages. An exception for hemp gummies and hemp beverages would align Florida’s hemp regulations with the FDA’s regulations, ensuring harmony between federal and state regulatory regimes and preventing disruption in the availability of hemp products that meet federal safety standards.

Second, further to the FDA’s regulations, many surrounding states allow the use of FDA-approved color additives in beverages, including hemp-infused beverages. The Proposed Rule’s prohibition against color additives in consumable hemp products across the board would put hemp businesses at a competitive disadvantage and impede interstate commerce. An exception for hemp beverages and hemp gummies, on the other hand, will create economic opportunities for hemp businesses and lead to fairer, freer business competition.

Third, Senate Bill 1676 limited consumable hemp products to persons who are 21 or older, and most hemp-infused beverages are generally marketed to adults only. Coloration is therefore not intended to appeal to children, and safety risks posed to children are mitigated. Prohibiting the use of color additives in hemp beverages is superfluous and does not serve Senate Bill's 1676 aims.

If the Department is not inclined to add an exception for hemp gummies and hemp beverages, it should consider an alternative exception for hemp beverages when sold in non-transparent packaging. Hemp beverages sold in opaque packaging do not appeal to children, so it is necessary to prohibit their coloration.

II. 5K-4.034(5)(i) & (5)(j) – Functional ingredients for coloration

Sections (5)(i) and (5)(j) prohibit ingredients that are permitted under 21 CFR 73A and/or 21 CFR 74A, thereby prohibiting functional and non-functional ingredients when used as color additives that are allowed under federal law. We think a better approach is to allow the use of functional ingredients for coloration, including ingredients permitted under 21 CFR 73A, while prohibiting the use of brightly colored synthetic additives in 21 CFR 74A that lack functional properties.

As currently drafted, the Proposed Rule poses significant business issues. First, the Proposed Rule could lead to Florida's hemp regulations being as restrictive as the prohibition on color additives in Florida's medical marijuana regulations, which would inappropriately liken hemp to marijuana and result in hemp gummies being indistinguishable from medical marijuana gummies.

Second, the Proposed Rule would be the first in the United States to blanketly prohibit color additives in finished hemp products, which would require manufacturers within and outside Florida to maintain separate production lines—increasing compliance costs and leading to inefficiencies and logistical challenges.

Third, because the Proposed Rule does not have a sell-through provision, existing inventories would be rendered immediately non-compliant and could not be sold in Florida.

III. 5K-4.034(6)(n)

Section (6)(n) requires that the certificate of analysis for hemp and consumable hemp extract products “shall state the name and address of the facility where the batch was processed, the current and valid permit number for the facility issued by a human health or food safety regulatory entity with authority over the facility, and that the facility meets the human health or food safety sanitization requirements of the regulatory entity as documented by the regulatory entity.”

This requirement is untenable and will be difficult to meet. It is highly unlikely that any laboratory will add to its certificate of analysis the permit number for the facility where the hemp batch was manufactured or processed, assuming that the laboratory can even obtain such information. Moreover, in some states, hemp

manufacturing is regulated by the department of agriculture, or some agency other than “the human health or food safety regulatory entity.” We recommend that this requirement be removed.

IV. 5K-4.034(9)(a)

Section (9)(a) prohibits marketing hemp and consumable hemp extract products using “words, initialisms, acronyms, phrases, colors or color combinations, visual patterns, logos, images, concepts, names, or slogans that duplicate, imitate, or bear a reasonable resemblance to words, initialisms, acronyms, phrases, colors or color combinations, visual patterns, logos, images, concepts, names, or slogans used in connection with commercially available branded products and services.”

While the purpose is laudable, the prohibition is overbroad. The prohibition applies whether or not the marketing used is appealing to children. Rather, section (9)(a) should be limited to the use of marketing that is intended to target or is attractive to children such that the marketing is confusing or misleading as to the product’s potentially intoxicating capabilities, especially because Fla. Stat. 581.217(3)(a) provides a definition for “attractive to children.” Similar qualifying language appears in section (9)(b).

V. 5K-4.034(9)(c)

Section (9)(c) prohibits marketing hemp and consumable hemp extract products using “[w]ording that uses street or slang words or names for marijuana, hemp, hemp extract, or the intoxicating effects of marijuana.”

The prohibition is overbroad, ambiguous, and difficult to enforce, and we recommend it be deleted. Further, the prohibition could have the unintended consequence of undermining Senate Bill 1676’s goals of ensuring consumer awareness and protecting consumer safety. By prohibiting marketing of hemp and consumable hemp extract products as intoxicating or for their “intoxicating effects,” the Proposed Rule risks consumers not being fully informed about the properties and potential effects of the products they are buying.

As an alternative, if the Department is not inclined to delete the provision, we recommend that a list be added of permissible wording that would not violate the provision. Permissible wording could include terms similar to “hard” when used in marketing alcoholic products that contain more alcohol than other alcoholic drinks. We would be happy to work together with the Department to develop permissible wording that does not compromise the intent of Senate Bill 1676.

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The Roundtable is grateful to the Department for its focus on the important topic of appropriately regulating hemp and consumable hemp extract products. We are available to collaborate with the Department so that the issues discussed above are resolved for the benefit of the hemp products industry in Florida and across the country. To that end, we respectfully urge you to include our suggested recommendations and we request that a public hearing on the Proposed Rule be held. Thank you for your consideration.

October 16, 2024

Page 4

Sincerely,

A handwritten signature in black ink, appearing to read 'Jonathan Miller', with a long horizontal flourish extending to the right.

Jonathan Miller
General Counsel
U.S. Hemp Roundtable

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