

# U.S. Hemp Roundtable

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250 West Main Street, Suite 2800, Lexington, KY 40507

December 28th, 2020

Kentucky Cabinet for Health and Family Services Department for Public Health  
Office of Legislative and Regulatory Affairs  
275 East Main Street 5 W-A  
Frankfort, KY 40621

Re: Public Comments to 902 KAR 45:190

To Whom It May Concern:

On October 26, 2020, we submitted comments to the regulations your agency promulgated under 902 KAR 45:190 concerning the manufacturing and sale of hemp-derived cannabidiol (CBD) products. (See Attachment 1). After consulting with other hemp stakeholders in the Commonwealth, we have supplemented and updated those comments below. We are hopeful that you may amend the regulations to ensure the greatest opportunity to Kentucky farmers and businesses while securing protections to consumers. We appreciate your consideration of the following recommendations:

1. Section 1. Definitions is missing the definition for “ingestible” which is a key term that will help to provide an improved opportunity for manufacturers to manufacture value-added CBD products within Kentucky while ensuring safety to the consumer. As the draft guidance currently stands, depending on interpretation, manufacturers may be limited to solely manufacturing ingredients and a small subset of finished products. Any other ingestible product, which accounts for over 80% of the CBD ingestible market, may need to be shipped out of the state for further formulation and packaging. In order to maintain value-added products within the Commonwealth of Kentucky, we suggest the following edits under Section (1) Definitions:
  - a. **(7) “Ingestible” means any consumable product capable of being ingested into the body.**
2. Section 2 (1) requires parties seeking to “manufacture, market, sell or distribute” CBD products to obtain an “Application for Permit to Operate a Food Plant or Cosmetic Plant.” This permit does not seem relevant to a retailer wishing to sell CBD or an out-of-state manufacturer. As such, we suggest the following edits:
  - a. A person **located in Kentucky** seeking to manufacture, market, sell or distribute a hemp-derived CBD ingestible or cosmetic product shall submit an Application for Permit to Operate a Food Plant or Cosmetic Manufacturing Plant, incorporated by reference 902 KAR 45:160, to the department. **Entities that only sell or distribute hemp-derived CBD ingestible or cosmetic products and do not manufacture such products, and do not add CBD to ingestible products onsite, are not required to obtain a permit.**
3. Section 3(2) requires six (6) point font labeling for any ingestible or cosmetic product label; however, a majority of products on the market, particularly many cosmetics and oils, require labels that are less than 12 square inches in size, making it difficult to include all the currently required information within this area. In accordance with Federal guidelines, we request the removal of the six (6) point font requirement for ingestible and cosmetic product labels in

Section 3(2) and urge the Cabinet to take a flexible approach to font size that is dependent on the size of the label, similar to federal requirements. As noted above, the majority of hemp and CBD products on the market require labels that are less than 12 square inches in size, and federal regulations established under 21 CFR Part 101 (for food and dietary supplements) and 21 CFR Part 701 (for cosmetics) provide the flexibility necessary to accommodate these smaller labels. If the Department maintains the current language, hemp and CBD 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.<sup>1</sup> As such, we recommend the following changes:

- a. **“An ingestible or cosmetic product label with a surface area greater than 12 square inches shall include, in a print no less than six (6) point font, or an ingestible or cosmetic product label with a surface area no more than 12 square inches shall include, in a print no less than four-in-one-half (4.5) point font, the following information...”**
4. Section 3(e) and Section 4(2)(c) require a statement that the CBD product complies with federal law concerning THC concentration. We think it is important to provide suggested terminology so that manufacturers and brands wishing to produce within the state comply with federal law and other state laws while still maintaining brevity. In addition, a manufacturer or brand should have the right to choose whether they want to simplify THC to simply read THC or provide a more accurate approach by describing THC in its appropriate scientific designation as  $\Delta$ -9-THC. As such 2(e) should read:
    - a. “A statement that the hemp-derived CBD product is within the federal legal limit of three-tenths of one percent (0.3%) tetrahydrocannabinol. **Examples may include: “contains no more than 0.3% THC” or “contains no more than  $\Delta$ -9-THC.”**”
  5. Section 3 (f) requires the total amount of cannabidiol per serving for ingestible products or the total amount per container for cosmetic products. We feel it is important to offer flexibility in product standardization as many brands formulate and market products for total cannabinoids or other cannabinoids rather than concentration of CBD per serving or container while maintaining legal thresholds of  $\Delta$ -9-THC. The following change provides more flexibility to in-state manufacturers seeking to provide products to brands while providing further clarification for consumers:
    - a. the total amount of cannabidiol **and/or cannabinoids** per serving for ingestible products or the total amount per container for cosmetic products.
  6. Section 3 (h) requires the statement or similar statements “Consult your physician or healthcare professional before use.” To further support the safe use of hemp and CBD products, we also suggest the inclusion of language that requires the advisory statement in Section 3(2)(h) to be “clear and conspicuous” as indicated below, while removing the statement from the mandated 6-pt font section. While federal regulations do not include such a requirement for warnings, we share the Cabinet’s desire to ensure the safe use of hemp and CBD products. We recommend the following changes:
    - a. **(h) 3. In a manner that is clear and conspicuous,** the statement or similar statements “Consult your physician or healthcare professional before use.”

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<sup>1</sup> 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.

7. Section 3 (i) requires an expiry, if any that would also be included under this 6-point font requirement. Most manufacturers print expirations on the physical bottles post-production as opposed to labels. This is a common practice for manufacturing that allows for reduced variations in labels and reductions in costs and is considered a norm practice to consumers. Therefore, we recommend the following adjustment:
  - a. An expiry, if any, **unless otherwise denoted on the product packaging.**
  
8. Section 3 (j) requires the Kentucky Hemp or Kentucky Proud logo or similar marketing denoting the product was produced in Kentucky. While we feel representing the Kentucky Hemp and/or Kentucky Proud brand is important to the growth of Kentucky's industry, this marketing need should be serviced elsewhere and not be a requirement on labels. There is already extremely limited space available on labels that must be utilized for items like warnings, product fact panels, ingredients and the like within the required font size. In many instances, this requirement is redundant when the name of the manufacturer required on the label is claiming a Kentucky address. Also, requiring an additional mark denoting the product's state of origin will be a hinderance to manufacturers seeking to provide services to brands outside of Kentucky that may have no desired marketing association with the state. This hindrance is counter-productive to the intention of keeping value-added production within the Commonwealth. As such, we recommend removing the section from the mandated list of labeling requirements under Section 3 (2) and creating an optional clause under Section 3 (3) that includes the following:
  - a. ~~(j)~~ **(4) The product's label may include** the Kentucky Hemp or Kentucky Proud logo or similar marketing denoting the product was produced in Kentucky.
  
9. The current Section 3 (3) limits the variation of tamper-proof seals that companies are already utilizing in the market; therefore, Section 3 (3) should be edited to read:
  - a. Each container of ingestible or cosmetic hemp-derived CBD product shall bear either **a tamper evident seal such as** a foil seal on the inside or a plastic sealant on the outside.

Sincerely,



Jonathan Miller  
General Counsel  
U.S. Hemp Roundtable

# 2020 U.S. HEMP ROUNDTABLE

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# U.S. Hemp Roundtable

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250 West Main Street, Suite 2800, Lexington, KY 40507

October 26, 2020

Kentucky Cabinet for Health and Family Services  
Department for Public Health  
275 East Main Street  
Frankfort, KY 40601

Re: Public Comments to 902 KAR 45:190

To whom it may concern:

We are deeply grateful to your agency, as well as to Governor Andy Beshear and his senior advisor, Rocky Adkins, for your responsiveness to issues we raised this summer about the need for regulatory clarity concerning the retail sale of hemp-derived cannabidiol (CBD) as a dietary supplement and additive to foods and beverages. The regulations you have promulgated at 902 KAR 45:190 provide explicit legal protection for the retail sale of ingestible CBD products, as well as critical regulatory protections for the health and safety of CBD consumers. We applaud you for once again putting Kentucky at the vanguard of national hemp policy.

We do, however, want to draw your attention to a few remaining issues with the regulations, and are hopeful that you would be willing to amend the regulations to ensure the greatest opportunity for Kentucky hemp farmers and small businesses, as well as the strongest protections and greatest options for CBD consumers:

1. Section 2 (1) requires parties seeking to “manufacture, market, sell or distribute” CBD products to obtain an “Application for Permit to Operate a Food Plant or Cosmetic Plant.” Such a permit would not seem relevant to a retailer who sells CBD, or to an out-of-state manufacturer who must comply with its own state’s permitting processes. Accordingly, we suggest the following edits to that section:

A person **located in Kentucky** seeking to manufacturer, market , sell, or distribute a hemp-derived CBD ingestible or cosmetic products shall submit an Application for Permit to Operate a Food Plant or Cosmetic Manufacturing Plant, incorporated by reference in 902 KAR 45:160, to the department. **Entities that only sell or distribute hemp-derived CBD ingestible or cosmetic products and do not manufacture such products, and do not add CBD to ingestible products onsite, are not required to obtain a permit.**

2. Section 3(e) requires a statement that the CBD product complies with federal law concerning THC concentration. We want to be sure that the following statement which complies with federal law and other state laws would be sufficient: **“Contains no more than 0.3% THC”**
3. Section 3(g) could potentially be read to require that a CBD product sold in Kentucky must be produced in Kentucky. From our previous discussions, we assume this is a drafting error, and to fix this, we suggest the edit below. If indeed this was intentional, we strongly recommend that it be adjusted as below as well: Such a rule would be inconsistent with Kentucky

law, would deny Kentucky consumers access to popular products, and could lead to a trade war with other states that could damage the ability for Kentucky farmers and businesses to sell their products to other state markets.

The Kentucky Hemp or Kentucky Proud logo or similar marking ~~that denotes~~, **provided** the product was produced in Kentucky.

4. Since there are numerous methods of tamper-proof sealing of products, and innovation in this area is always contemplated, we suggest the following edit to Section 3 (3):

Each container of ingestible or cosmetic hemp-derived CBD product shall bear ~~either~~ **a tamper evident seal such as** a foil seal on the inside or a plastic sealant on the outside.

Please don't hesitate to contact me if you have any questions or would otherwise like to discuss. Thanks again for your attention to these important issues for Kentucky farmers and businesses.

Sincerely,



Jonathan Miller  
General Counsel, U.S. Hemp Roundtable

Cc: Rocky Adkins  
Leanne Applegate  
Kelli Rodman  
Julie Brooks  
Donna Little