CABINET FOR HEALTH AND FAMILY SERVICES

Department for Public Health
Division of Public Health Protection and Safety

(Amended After Comments)

902 KAR 45:190. Hemp-derived cannabinoid[cannabidiol] products and labeling requirements.

RELATES TO: KRS 217.015, 217.037, 217.025, 217.035, 217.155, 260.850

STATUTORY AUTHORITY: KRS 217.125, 217.127, 217.135

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 to 217.215. KRS 217.125(2) requires the secretary to provide by administrative regulation a schedule of fees for permits to operate and for inspection activities carried out by the cabinet pursuant to KRS 217.025 through 217.390. KRS 217.135 authorizes the secretary to establish food standards by administrative regulation including a reasonable definition, standard of identity, and designation of optional ingredients that shall be named on the label. This administrative regulation establishes the registration process to utilize hemp-derived cannabinoid[cannabidiol] products in foods and cosmetics, the labeling requirements for products containing hemp-derived cannabinoid[cannabidiol], and methods for use of hemp-derived cannabinoid[cannabidiol] as an additive to food products.

Section 1. Definitions. (1) "Approved source" means a Kentucky hemp grower,
processor, or handler licensed by the Kentucky Department of Agriculture, or an out of
state hemp grower, processor, or handler who is duly authorized to produce hemp under
the laws of their jurisdiction.

(2) "Cabinet" is defined by KRS 217.015(3).

(3) "Cannabinoid" means a non-intoxicating

compound found in the hemp plant Cannabis sativa.

(4) "Cosmetic" is defined by KRS 217.015(7).

(5) "Department" means the Kentucky Department for Public Health.

(6) "Food service establishment" is defined by KRS 217.015(21).

(7) "Hemp" is defined by KRS 260.850(5).

(8) "Home-based processor" is defined by KRS 217.015(56).

(9) "Person" is defined by KRS 217.015(32).

Section 2. Permits. (1) A person located in Kentucky seeking to manufacture, market, sell,
or distribute a hemp-derived ingested or cosmetic cannabinoid product 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.

(2) The permit shall be:

(a) Nontransferable in regards to person or address; and
(b) Renewed annually.

(3) The fee shall be paid in accordance with:

(a) 902 KAR 45:180, for a food processing establishment;
(b) 902 KAR 45:180, for a cosmetic manufacturer; and
(c) 902 KAR 45:110, Section 1(3), (4), and (5), for a food service establishment.
(4) Ingestible hemp-derived cannabinoid products shall not be manufactured, marketed, sold, or distributed by a home-based processor.

Section 3. Product labeling. (1) Each hemp-derived cannabinoid[CBD] product manufactured, marketed, sold, or distributed in the Commonwealth shall be labeled in accordance with KRS 217.037 and this administrative regulation.

(2) An ingestible or cosmetic product label shall include, in a print no less than six (6) point font, the following information:

(a) A statement of identity or common product name that shall be stated upon the principal display panel of the label;

(b) The net quantity of contents expressed in both standard English and metric units of measurement located in the lower thirty percent (30%) of the principal display panel of the label parallel to the base of the container;

(c) The ingredients of the hemp-derived cannabinoid[CBD] product, in descending order of predominance by weight;

(d) The name of the manufacturer or distributor;

(e) A statement that the hemp-derived cannabinoid[CBD] product is within the federal legal limit of three-tenths of one percent (0.3%) delta-9 tetrahydrocannabinol;

(f) The total amount of cannabinoid[cannabinoid] per serving for ingestible products, or the total amount per container for cosmetic products;

(g) Suggested use instructions or directions, including serving sizes;

(h) The statement, or a similar statement, "Consult your physician or healthcare professional before use"; and

(i) An expiration date, if any;
(j) The Kentucky Hemp or Kentucky Proud logo or a similar marking that denotes the product was produced in Kentucky.

(3) An ingestible or cosmetic product that has a total area of twelve (12) square inches or less available to bear labeling shall be labeled in accordance with subsection (2) of this section except the print may be smaller than six (6) point font but shall not measure less than 1/32 of an inch in height.

(4) The labeling requirements of subsection (2) of this section shall not be printed unduly small in relation to the total area available to bear labeling in order to accommodate unrequired information such as logos, photographic representation of the product, or additional marketing copy.

(5) Each container of ingestible or cosmetic hemp-derived cannabinoid[CBD] product shall have a tamper evident seal[[bear either a foil seal on the inside or a plastic sealant on the outside].

(6)[(4)] Product labeling or advertising material for any hemp-derived cannabinoid[CBD] product shall not bear any implicit or explicit health claims stating that the product can diagnose, treat, cure, or prevent any disease.

Section 4. Hemp-derived ingestible cannabinoid products[CBD product as a food additive]. (1) Hemp-derived cannabinoid[CBD] may be added to an ingestible product during the manufacturing process or prior to retail sale at a food service establishment.

(2) The hemp-derived cannabinoid shall be obtained from an approved source.

(3) The food processor or food service establishment shall obtain a valid certificate of analysis from the approved source and provide a copy upon inspection.
(4) Food or ingestible product shall not contain a total delta-9 tetrahydrocannabinol concentration of more than three-tenths of one percent (0.3%) on a dry weight basis or contain tetrahydrocannabinol as the primary cannabinoid.

(5) A food service establishment offering hemp-derived cannabinoid[CBD] products in a finished food product shall provide the following information to consumers upon request:

(a) The common name of the product;

(b) The manufacturer or distributor of the product; and

(c) A statement that the hemp-derived cannabinoid[CBD] product is within the federal legal limit of three-tenths to one percent (0.3%) delta-9 tetrahydrocannabinol.
902 KAR 45:190

REVIEWED:

[Signature]

Steven J. Stack, MD, MBA
Commissioner, Department for Public Health

Date: 2/2/2021

APPROVED:

[Signature]

Eric C. Friedlander
Secretary, Cabinet for Health and Family Services

Date: 2/3/2021
REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 902 KAR 45:190

Agency Contact: Julie Brooks, (502) 564-3970, julied.brooks@ky.gov or Donna Little, (502) 564-6746, CHFSregs@ky.gov

(1) Provide a brief summary of:
   (a) What this administrative regulation does: This administrative regulation establishes the registration process to utilize hemp-derived cannabidiol (CBD) products in foods and cosmetics, the labeling requirements for products containing hemp-derived cannabidiol, and methods for use of hemp-derived cannabidiol as an additive to food products.

   The Amended After Comments version of this administrative regulation expands hemp-derived extracts to include all cannabinoids by replacing “cannabidiol” with “cannabinoid” throughout the administrative regulation, adds the requirement that the hemp-derived cannabinoid be from an approved source, adds definitions for “approved source”, “cannabinoid”, and "hemp", and updates the labeling requirements.

   (b) The necessity of this administrative regulation: With the passage of the federal Agriculture Improvement Act of 2018, hemp-derived cannabinoid products are one of the fastest growing manufactured food or cosmetic product markets. This administrative regulation is necessary to ensure the safety of food and cosmetic products containing hemp-derived cannabinoids.

   (c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 217.037 requires that all foods and cosmetics shall conform to the Fair Packaging and Labeling Act, and the administrative regulations promulgated thereto. KRS 217.125(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act.

   (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes the requirements for using hemp-derived cannabinoids in food and cosmetics, and ensures these products are properly labeled.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
   (a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.

   (b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

   (c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

   (d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.
(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The number of businesses affected by this administrative regulation is unknown. A web search yielded a list of twenty (20) businesses producing hemp-derived CBD or offering hemp-derived CBD products for sale.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
   (a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: Individuals interested in marketing, manufacturing, selling, or distributing hemp-derived cannabinoid ingestible and cosmetic products will need to be aware of the additional application and permitting requirements, and will need to ensure all products comply with the labeling requirements of this administrative regulation.
   (b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): Those persons seeking to manufacture ingestible hemp-derived cannabinoid products will pay the fee established in 902 KAR 45:180. Those persons seeking to manufacture a hemp-derived cannabinoid cosmetic product will pay the $125 fee as established in 902 KAR 45:180. A retail food service establishment offering hemp-derived cannabinoid as an additive to prepared food will pay the fee established in 902 KAR 45:110.
   (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Those offering hemp-derived food or cosmetic products will be able to provide a safe product to the consumer.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
   (a) Initially: What is the costs associated with this new regulation? The department will need to hire additional staff to oversee the permitting and inspection process related to this administrative regulation. The salary for this staff could range between $38,770 to $62,033 per year.
   (b) On a continuing basis: The ongoing costs associated with this administrative regulation could be between $38,770 to $62,033.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State general fund dollars, and revenue received from the permitting fees.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment: An increase in funding is necessary to implement this administrative regulation. The department will incur costs associated with hiring staff to perform the permitting and inspection processes required by this administrative regulation.
(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. The fee required to manufacture, market, sell, or distribute hemp-derived cannabinoid food or cosmetic products will be paid in accordance with the application fee regulation. A separate fee is not required.

(9) TIERING: Is tiering applied? (Explain why or why not.) Tiering is not applied. The permitting and labeling requirement will impact those seeking to produce ingestible and cosmetic hemp-derived cannabinoid products equally.
FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation: 902 KAR 45:190

Agency Contact: Julie Brooks, (502) 564-3970, julied.brooks@ky.gov or Donna Little, (502) 564-6746, CHFSregs@ky.gov

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation will impact the Food Safety Branch in the Division of Public Health Protection and Safety within the Department for Public Health, Cabinet for Health and Family Services.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 217.037, 217.125, 217.127, 217.135, and 217.145.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
   (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation does not generate revenue.
   (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation does not generate revenue.
   (c) How much will it cost to administer this program for the first year? It will cost between $38,770 to $62,033 to administer this program in the first year.
   (d) How much will it cost to administer this program for subsequent years? It will cost between $38,770 to $62,033 to administer this program in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.
   Revenues (+/-):
   Expenditures (+/-):
   Other Explanation:
STATEMENT OF CONSIDERATION  
RELATING TO 902 KAR 45:190  
Cabinet for Health and Family Services  
Department for Public Health  
Division of Public Health Protection and Safety

Amended After Comments

(1) A public hearing on 902 KAR 45:190 was held on December 21, 2020, at 9 a.m. via the Zoom Cloud Meetings platform. In addition to those who attended the public hearing, written comments were received during the public comment period.

(2) The following individuals provided comments via the public comment process:

<table>
<thead>
<tr>
<th>Name and Title</th>
<th>Agency/Organization/Entity/Other</th>
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<tbody>
<tr>
<td>Jim Adrianse</td>
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<td>Rona Alexander, Owner</td>
<td>Alive With Hemp, LLC</td>
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<td>Reno Aitschul</td>
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<td>Rhonda Archbold</td>
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<td>Melissa Arnold</td>
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<td>Phillip Arvin, hemp grower</td>
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<td>Cindy Atchison</td>
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<td>Janet Barger</td>
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<td>Melissa Barnes</td>
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<td>Veronica Belsuzarri</td>
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<td>Shane Benson*, Compliance Attorney</td>
<td>Turning Point Brands</td>
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<td>Steve Bevan, Partner</td>
<td>OCan Group</td>
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<td>Mary Bieda</td>
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<td>Joseph A. Bilby, General Counsel</td>
<td>Kentucky Department of Agriculture</td>
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<td>Ann Boone</td>
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<td>Julie Brooks, Regulation Coordinator</td>
<td>Kentucky Department for Public Health</td>
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<td>Melissa Broome</td>
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<td>Scott Brown, KDA licensed grower</td>
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<td>Andrea Burnside</td>
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<td>Jamie Lynn Byram, Ph.D.</td>
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<td>Cathy Chapman</td>
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<td>Bonnie Cheung</td>
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<td>Justin Cline, CEO</td>
<td>Ancient Aromas™</td>
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<td>John Clopein</td>
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<td>Betty Cole</td>
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Ron Conyea, Owner
Sam Cox, Government Affairs
Gail Cummins
Amanda Darlington, Director
Government Relations
Ragan Davies
Cindy Deckard
Matthew Dykes,
Co-Owner and Marketing Director
Bunny Felsps
Joy Forrest
Keiona Frye
Charles George, Executive Director

Julie Geiger
Lee Gillis
Amy Glaser, Pharmacist
Brett Goldman, Partner
Karen Grant
Joe Graviss, Former State Representative
Alyson Hall
Tammy Hall
Dave Hendrick
Lana Hendricks
Jeanne Himber
Fran Hoagland

Mark Hutchison, General Manager
Kentucky Heritage Hemp Company
Cydney Jackson
Howard T. Kendrick
Debbie Kiser
Bill Kreidler
Rose Kreidler
Marty Kuhl
Melinda Laudermilk
Sue Lauria
Earl and Geneva Lewis
Jesse Lucas

Brian Luftman, Founder and President
American Farm Investors
Jo Luthe
Tammie Mabe
Austin MacGinnis
Lucy MacGinnis
Susan Maynard
Charlotte McClure
Kim McDonald
Jonathan Miller, General Counsel

Conyea Farms
Kentucky Cannabis Company
Council for Responsible Nutrition
502 Hemp/502 Wellness
Wine & Spirits Wholesalers of Kentucky
Alexandria Drugs
OCan Group

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Sally Moore
Rita Mulkins
Mandy Myers
Brenda Nichols
Jeff Oldham
James Patrick
Patricia Pendley
Lisa Ramsey
Rebecca Ray
BJ Reneau
Melissa Rice
Walter Riker
Jennifer Roe
Jim Rogers
Annie Rouse, Chief Operating Officer
Kristel Rush
Alex Russell, President & CEO
Patti Ryan
Vickie Sageser
Robert Schraut
Erica Schroeder
Doug Schuble, Affiliate
Sabrina Shafer
Jennifer Shuttleworth
Eileen Slater
Sandy Smith
Kent Snodgrass
Lesley Spencer, Brand Manager
Ric Stofer
Judith Swift
Delphia Taylor, Owner
Rick Trojan, President
Tristen Walters
Wayne Ware
Linda Welch
MaryLinda Wells
Shirley Wiseman
Laura Wolfrom

*Attended the public hearing but did not provide comment
The following individual from the promulgating administrative body responded to the public comments:

Name and Title | Agency/Organization/Entity/Other
--- | ---
Julie Brooks, Regulation Coordinator | Department for Public Health

Cabinet for Health and Family Services

SUMMARY OF COMMENTS AND AGENCY’S RESPONSES

(1) Subject: Support for administrative regulation

(a) Comment: Cindy Deckard commented: "Plesse pass legalization of medicinal marjuania. I have chronic pain and need the inflammatory attributes of this product."

(a) Comment: Lesley Spencer, Brand Manager, Kentucky Cannabis Company, commented: "I feel very strongly that the proposed CBD product & label regulation must be passed. This regulation will help protect consumers and the industry we fought so hard to bring to Kentucky!"

(a) Comment: Andrea Burnside; Melissa Barnes; Austin MacGinnis; Patricia Pendley; Betty Cole; Patti Ryan; BJ Reneau; Reno Altschul; Cydney Jackson; Ric Stofer; Dave Hendrick; Rita Mulkins; Debbie Kiser; Sabrina Shafer; Erica Schroeder; Sally Moore; Gail Cummins; Shirley Wiseman; Jamie Lynn Byram Ph.D.; Sue Lauria; Janet Barger; Susan Maynard; Jeff Oldham; Tammie Mabe; Jennifer Roe; Tammy Hall; Jennifer Shuttleworth; Tristen Walters; Jesse Lucas; Veronica Belsuzarri; Jim Adrianse; Vicki Sageser; Judith Swift; Walter Riker; Julie Geiger; Karen Grant; Kim McDonald; Kristel Rush; Lana Hendricks; Laura Wolfrom; Lee Gillis; Linda Welch; Lisa Ramsey; Lucy MacGinnis; Melinda Laudermilk; Melissa Arnold; Melissa Broome; Earl and Geneva Lewis; John Clopein; Cindy Atchison; Jeanne Himber; Sandy Smith; Charlotte McClure; Kent Snodgrass; Bunny Felps; Keiona Frye; Ann Boone; Rhonda Archbold; Eileen Slater; Rose Kreidler; Mary Bieda; Ragan Davies; Jim Rogers; Robert Schrout; Mandy Myers; Cathy Chapman; Brenda Nichols; Wayne Ware; Bonnie Cheung; Melissa Rice; Amy Glaser, Pharmacist, Alexandria Drugs; Allyson Hall; Marty Kuhl; Joy Forrest; Bill Kreidler; Howard T. Kendrick; and MaryLinda Wells commented: "I am writing to you today to let you know I am in favor of implementing the proposed 902 KAR 45_190 CBD labeling regulation. Doing so would protect CBD consumers and the industry, as well as, clearing up the gray area and addresses CBD used as a food additive at the restaurant/bar level. This regulation is a huge WIN for the hemp industry AND for consumers."

(a) Comment: Rebecca Ray commented: "I hope the bill to accurately label CBD products will pass. As it has become a popular thing to put on a label, there will be companies who take advantage. Consumers should know what they are buying and be able to compare with knowledge."
(b) Response: The cabinet appreciates the support for this administrative regulation. The cabinet is not amending this administrative regulation in response to these comments.

(2) Subject: Labeling requirements

(a) Comment: James Patrick commented: “I would like to express my support for the effort by KCC to create label regulations on CBD products. I feel it is important for transparency and for public health that labels contain complete and accurate information and suggested usage.”

(a) Comment: Fran Hoagland commented: “It's so important that labeling and standardization be used with CBD products. I strongly encourage you to pass regulations so the CBD industry can eliminate false claims and make CBD brands to follow product and label requirements.”

(a) Comment: Amanda Darlington, Director, Government Relations, Council for Responsible Nutrition (CRN), commented: “Section 3: Product Labeling

Original language with proposed strikethroughs and additional language:

(1) Each hemp-derived CBD product manufactured, marketed, sold, or distributed in the Commonwealth shall be labeled in accordance with KRS 217.037 and this administrative regulation or federal regulations related to food, cosmetics and dietary supplements.

(c) The ingredients of the hemp-derived CBD product, in descending order of predominance by weight listed in the ingredients statement;
(j) if the hemp or hemp product is manufactured in the state of Kentucky, the product can denote the “Kentucky Hemp” or “Kentucky Proud” logo or a similar marking that denotes the product was produced in Kentucky.
(3) Each container of ingestible or cosmetic hemp-derived CBD product shall bear either a foil-seal on the inside or a plastic-sealant on the outside.

“The purpose of CRN's proposed revisions is to provide for better clarity and consistency with current Federal Food and Drug Administration (FDA) labeling and packaging requirements and regulation of dietary supplements overall.

“Specifically, adding "or federal regulations related to food, cosmetics and dietary supplements” captures how food, cosmetics and dietary supplements are currently and extensively regulated by FDA under the federal Food, Drug and Cosmetic Act.² Without this language included, inconsistency and conflict arise because there are additional and specific labeling requirements for dietary supplements that are not covered in this proposed regulation.

“Moreover, section (3)(c), as proposed, is inconsistent with current federal requirements as not all of the ingredients in a dietary supplement are listed together in descending order of predominance by weight, as some are listed separately per federal nutrition labeling requirements... In the promotion of better consistency between state and federal regulation of dietary supplement products CRN proposes the above inclusion in section (3)(1) and section (3)(c).”
Comment: Sam Cox, Government Affairs, Kentucky Cannabis Company commented: “The one thing this regulation leaves out that we would like to see is a QR code or scanned bar code requirements. This was in House Bill 593 and it would allow a consumer to access that bar code or QR code and it would take that consumer to a Certificate of Analysis.”

Comment: Joe Graviss, former State Representative, commented: “Please include the QR Code on the label that will send the consumer to an all-inclusive web page that lists all the ingredients, strengths, processes, manufacturers, etc. because the labels are too small to print everything we need on them and the QR Code can easily house all that please. Basically the items we said to list in 21RS BR 141 CBD labeling bill that were listed as needed to be listed please.”

Comment: Delphia Taylor, Owner, 502 Hemp, LLC, commented: “Furthermore, there is no mention of testing criteria being available for the public to view in the new proposed rules. If the manufacturer and/or seller isn’t having the products tested, then the label specifications mentioned above don’t really matter. There are a lot of sellers that are skimming mgs on their containers and the ones that do have their products tested don’t even know how to read the tests to ensure the accuracy. The FDA only requires 10% variance on mgs, aren’t even close to the 10% variance. Typically that testing is done at the manufacturer level. If small retailers are selling products not meeting FDA label requirements and aren’t required to show their testing certificate, then there is still no regulation in the Kentucky hemp industry. There are an obscene amount of mom and pop processors that are making CBD products in their homes/barns and not even bothering to have it tested for milligram consistency. I doubt they even have a processing license through the KDA. I worry about the general public that buys these products and are being taken advantage of. Maybe requiring a the processors’ license number to be included on the label would help?”

Comment: Annie Rouse, Chief Operating Officer, OP Innovates; Mark Hutchison, General Manager, Kentucky Heritage Hemp Company; Scott Brown, KDA licensed grower; Alex Russell, President & CEO, Greenman Gardens, Inc.; Rick Trojan, President, Hemp Industries Association; Brian Luftman, Founder and President, American Farm Investors; Jo Luthe; Matthew Dykes, Co-Owner and Marketing Director, 502 Hemp/502 Wellness; Doug Schuble, Cornbread Hemp; Phillip Arvin, hemp grower; Jonathan Miller, General Counsel, US Hemp Roundtable; Delphia Taylor, Owner, 502 Hemp, LLC; Brett Goldman and Steve Bevan, Partners, OCan Group; Ron Conyea, Owner, Conyea Farms; and Justin Cline, CEO, Ancient Aromas™ commented: “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.

“As such, we recommend the following changes:

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 the following information...”

“Section 3(e) requires 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 δ-9-THC. As such 2(e) should read:

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 δ-9-THC.”

“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 δ-9-THC. The following change provides more flexibility to in-state manufacturers seeking to provide products to brands while providing further clarification for consumers:

the total amount of cannabidiol and/or cannabinoids per serving for ingestible products or the total amount per container for cosmetic products.

“...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:

An expiry, if any, unless otherwise denoted on the product packaging.

“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:

(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.

“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: Each container of ingestible or cosmetic hemp-derived CBD product shall bear either a tamper evident seal such as a foil or plastic seal on the inside or a shrink tube on the outside.”

(a) Comment: Annie Rouse, Chief Operating Officer, OP Innovates; Mark Hutchison, General Manager, Kentucky Heritage Hemp Company; Scott Brown, KDA licensed grower; Rick Trojan, President, Hemp Industries Association; Brian Luftman, Founder and President, American Farm Investors; Jo Luthe; Matthew Dykes, Co-Owner and Marketing Director, 502 Hemp/502 Wellness; Doug Schuble, Cornbread Hemp; Phillip Arvin, hemp grower; Jonathan Miller, General Counsel, US Hemp Roundtable; Delphia Taylor, Owner, 502 Hemp, LLC, and Justin Cline, CEO, Ancient Aromas™ commented:

"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:

(h) 3. In a manner that is clear and conspicuous, the statement or similar statements “Consult your physician or healthcare professional before use.”

(a) Comment: Joseph A. Bilby, General Counsel, Kentucky Department of Agriculture, commented: “... your agency's proposed administrative regulation, 902 KAR 45:190 ... is a step in the right direction. That said, there are a few aspects of the proposed regulation that my colleagues and I believe warrant amendment. First, we suggest removing the requirement that a product label must include “[t]he Kentucky Hemp or Kentucky Proud logo or a similar marking that denotes the product that was produced in Kentucky.” See Section 3(2)(j). Such a requirement is problematic for several reasons. For one, the Kentucky Proud logo does not state or imply anything about whether a labeled product is safe for use; it merely indicates that a product meets the definition of a "Kentucky-grown agricultural product" as that phrase is defined in KRS 260.016. For another, Kentucky Proud (and the Kentucky Hemp logo, for that matter) is and always has been a voluntary-based membership program, and we do not believe it would be appropriate to require, even directly, mandatory participation on the part of any agricultural producers or
agribusinesses. In other words, some manufacturers that are eligible to display the Kentucky Proud or Kentucky Hemp label on their products choose not to do so, and we do not believe it would be appropriate to require those manufacturers to display a label that is not consistent with their chosen marketing strategies.

"Second, we suggest amending the text of Section 4 so that it contains the following addition:

Product labeling or advertising material for any hemp-derived CBD product shall not bear any implicit or explicit health claims stating that the product can diagnose, treat, cure, or prevent any disease unless the product has been so approved by the United States Food and Drug Administration."

(a) Comment: Jonathan Miller, General Counsel, US Hemp Roundtable, commented: "Section 3(2)(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".

"Section 3(2)(g) could potentially be read to require that a CBD product sold in Kentucky must be produced in Kentucky. ...we assume this is a drafting error... If indeed this was intentional, we strongly recommend that it be adjusted... 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.

"Since there are numerous methods of tamper-proof sealing of products, ... 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..."

(b) Response: The Food Safety Branch in the Kentucky Department for Public Health, Cabinet for Health and Family Services, does not oversee the processing and labeling of dietary supplements produced in the state. The additional language suggested by the Council for Responsible Nutrition to cite to federal regulations related to food, cosmetics and dietary supplements is unnecessary. The cited statute, KRS 217.037, requires compliance with "the federal act and regulations related thereto".

The cabinet appreciates the clarification on the Kentucky Proud and Kentucky Hemp logo process from the Kentucky Department of Agriculture.

The cabinet agrees that linkage to a certificate of analysis from an independent testing laboratory would ensure products produced or sold in the state are within the federal legal limit of three tenths of one percent (0.3%) delta-9 tetrahydrocannabinol and ensure product safety. However, requiring a QR code or scannable bar code on the label may place an undue burden on small producers and manufacturers. The cabinet will address this issue by adding a definition for an "approved source" and requiring that the hemp-derived cannabinoid be from an approved source with a certificate of analysis available.
upon inspection.

The suggested change to add reference to product approval by the Food and Drug Administration (FDA) is not necessary. At this time, the FDA has not approved cannabidiol for use in foods. Should the FDA allow a health claim on these products the department would seek to transfer regulation back to the FDA.

The cabinet agrees the requirement for the label to have no smaller than a six (6) point font may be burdensome to those producers utilizing smaller packaging. The cabinet does allow smaller print on labels for food or cosmetic products when the total package size is smaller than twelve (12) square inches.

The cabinet is amending this administrative regulation in response to some of these comments.

(3) Subject: Suggested regulatory language

(a) Comment: Amanda Darlington, Director, Government Relations, Council for Responsible Nutrition (CRN), commented: "CRN recommends the Kentucky Department of Public Health to incorporate a definition of hemp that mirrors the Agriculture Improvement Act of 2018 (commonly referred to as the 2018 Farm Bill)—namely that “hemp” is defined 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-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis” in the definition section of this proposed regulation. Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

"Cannabidiol or CBD means the naturally occurring phytocannabinoid cannabidiol found in hemp and can be utilized as the definition of CBD for this proposed regulation as well...

"Section 4. Hemp-derived ingestible CBD product as a food additive. 

Original language with proposed strikethroughs and additional language: 

Section 4. Hemp-derived ingestible CBD product as a food additive.

(1) Hemp-derived CBD may be added to an ingestible product during the manufacturing process, and manufactured, marketed, sold, and distributed in this state by out of state producers if the product meets this state's or another states hemp product quality requirements, or prior to retail sale at a food service establishment.

"The purpose of CRN's proposed revisions provide for better clarity. Specifically, the state's intent to regulate state-based manufacturers of food, dietary supplements and cosmetics that contain hemp-derived CBD, not solely as a “food additive” is better understood with the strikethrough of “as a food additive” in the title of section 4.

"Moreover, the state's intent to regulate state-based manufacturers of food, dietary
supplements and cosmetics that contain hemp-derived CBD is better understood and creates opportunities for a diversified marketplace with language, in section 4(1) that includes the ability of 'out of state producers' to "manufacture, market, sell, and distribute" hemp-derived CBD products in the state, as long as the person complies with Kentucky or another states' "quality requirements". The testing of hemp products is important for quality control and meeting the threshold requirements of the 2018 Farm Bill definition of "hemp".

(a) Comment: Annie Rouse, Chief Operating Officer, OP Innovates; Mark Hutchison, General Manager, Kentucky Heritage Hemp Company; Scott Brown, KDA licensed grower; Alex Russell, President & CEO, Greenman Gardens, Inc.; Rick Trojan, President, Hemp Industries Association; Brian Luftman, Founder and President, American Farm Investors; Jo Luthe; Matthew Dykes, Co-Owner and Marketing Director, 502 Hemp/502 Wellness; Doug Schuble, Cornbread Hemp; Phillip Arvin, hemp grower; Jonathan Miller, General Counsel, US Hemp Roundtable; Delphia Taylor, Owner, 502 Hemp, LLC; Brett Goldman and Steve Bevan, Partners, OCAn Group; Ron Conyea, Owner, Conyea Farms; and Justin Cline, CEO, Ancient Aromas™ commented: "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:

"(7) "Ingestible" means any consumable product capable of being ingested into the body."

(b) Comment: Julie Brooks, Regulation Coordinator, Kentucky Department for Public Health, commented: "After discussions with the Kentucky Department for Agriculture regarding the regulation of the hemp industry in Kentucky it is clear that cannabidiol, or CBD, is just one variety of hemp-derived cannabinoid available as a potential ingestible or cosmetic product. There are products on the market that contain cannabigerol (CBG) or cannabinol (CBN). It is for this reason the regulation should cover all hemp-derived cannabinoids that may come onto the market.

"In addition, to help ensure product safety, the allowable concentration of the hemp-derived cannabinoid should be measured on a dry weight basis. This will allow for a consistent analysis of the amount of cannabinoid in the finished product. Products should also not contain tetrahydrocannabinol (THC) as the primary cannabinoid."

(b) Response: The cabinet agrees it is important to ensure all products that contain any form of a hemp-derived cannabinoid marketed or sold in the state are within the federally allowed limit of three tenths of one percent (0.3%) delta-9 tetrahydrocannabinol.

As used in this administrative regulation, the term "ingestible" is the standard dictionary meaning and the cabinet does not agree that further definition of the term is necessary.
To help ensure a consistent understanding of the term “hemp,” the cabinet will cite to the current state definition in KRS 260.850.

The cabinet is amending this administrative regulation in response to some of these comments.

(4) Subject: Permit requirements

(a) Comment: Jonathan Miller, General Counsel, US Hemp Roundtable, commented: “Are out of state entities required to be permitted in Kentucky? Suggested wording changes to Section 2(1) to clarify that the permit only requirements are for in-state entities only. Also suggested adding a statement that those that sell or distribute produce only are not required to obtain a permit.”

(a) Comment: Rona Alexander, Owner, Alive With Hemp, LLC, commented: “Will you ONLY be allowing Industrial Hemp CBD that is grown in Kentucky to be sold in KY? I would like clarification as to if you will allow Industrial Hemp CBD grown in other states or countries to be sold in KY.”

(a) Comment: Amanda Darlington, Director, Government Relations, Council for Responsible Nutrition commented: “CRN suggests a clarification to this section [Section 2] and re-write as follows.

Original language: (1) A person 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 in 902 KAR 45:160, to the department.

“New language proposal: (1) If a person seeks to operate a food, dietary supplement or cosmetic manufacturing plant in the state that manufactures a product containing hemp-derived CBD, they must apply for a permit from the Kentucky Department of Public Health.

“The purpose of CRN’s proposed revisions is to provide for better clarity, in that this language would distinctly authorize the state to require persons who manufacture hemp-derived CBD products in the state of Kentucky to register their manufacturing facilities with the state, while excluding from the registration and permit requirement those persons who are only selling or marketing a hemp-derived CBD product in the state of Kentucky, but manufacture their products in another state.”

(a) Comment: Annie Rouse, Chief Operating Officer, OP Innovates; Mark Hutchison, General Manager, Kentucky Heritage Hemp Company; Scott Brown, KDA licensed grower; Alex Russell, President & CEO, Greenman Gardens, Inc.; Rick Trojan, President, Hemp Industries Association; Brian Luftman, Founder and President, American Farm Investors; Jo Luthe; Matthew Dykes, Co-Owner and Marketing Director, 502 Hemp/502 Wellness; Doug Schuble, Cornbread Hemp; Phillip Arvin, hemp grower; Jonathan Miller, General Counsel, US Hemp Roundtable; Delphia Taylor, Owner, 502 Hemp, LLC; Brett
Goldman and Steve Bevan, Partners, OCan Group; Ron Conyea, Owner, Conyea Farms; and Justin Cline, CEO, Ancient Aromas™ commented: “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 of 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 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.”

(a) Comment: Delphia Taylor, Owner, 502 Hemp, LLC, commented: “Additional thoughts, if the state is going to require sellers of CBD products to obtain a license, it will harm many retail locations. There are so many companies selling CBD products, places like Rainbow Blossom, Kroger, CVS, TJ Maxx, hair salons, vape stores, veterinarians, pain managements, wellness centers, farmer’s markets, wholesale distributors, internet companies, florists, spas, gas stations, independent direct sales associates for multi-level marketing companies, doctor’s offices, etc… All of these companies are already paying Kentucky sales tax (or should be) and making them obtain another license would be a travesty to the entire hemp industry in Kentucky. Which in turn hurts the Kentucky farmer.

“These new proposed rules will end up hurting small businesses that make products like bath bombs, lotions, soaps, that use legal hemp extract in their products. If the cost of the license is too high, then many won’t be able to continue. Which means larger Kentucky retailers will look to out of state processors/makers to avoid the nuances of Kentucky’s rules and regulations. This again gives other states an advantage in the industry and will cause small Kentucky businesses to close. Small businesses are already ravaged by the pandemic and forced closures and it is a concern of mine that these regulations will cause even more harm. This year was tough for small businesses. Most are barely able to keep their doors open. Making Hemp and CBD products help them stay in business. I know my company works with other local businesses and I worry about finding a new out of state supplier.”

(b) Response: The Food Safety Branch in the Kentucky Department for Public Health agrees the proposed new administrative regulation is not clear on who must obtain a permit. Products from out of state will be allowed to be sold in Kentucky provided they are labeled in accordance with the regulation and the out of state grower, processor, or handler is able to provide a valid certificate of analysis of the product. The out of state vendor will not need a KY specific permit.

The cabinet is amending this administrative regulation in response to some of these comments.
(5) Subject: Alcoholic beverages that contain cannabidiol

(a) Comment: Charles George, Executive Director, Wine & Spirits Wholesalers of Kentucky commented: “Our members distribute alcoholic beverage products to retailers all across Kentucky. Some of them have been approached about selling and distributing CBD-infused beverages. It appears the regulation issued on October 8 (902 KAR 45:190) would allow those products to be sold in Kentucky. What if the CBD-infused beverage also contains alcohol? Is it allowed to be sold in Kentucky?"

(b) Response: The sale of products containing alcohol is not under the jurisdiction of the Department for Public Health. This regulation is specific to the labeling requirements for ingestible products and cosmetics that contain CBD.

The cabinet is not amending this administrative regulation in response to this comment.

Summary of Statement of Consideration and Action Taken by Promulgating Administrative Body

A public hearing on 902 KAR 45:190 was held on December 21, 2020, at 9 a.m. via the Zoom Cloud Meetings platform. In addition to those who attended the public hearing, written comments were received during the public comment period. The Cabinet for Health and Family Service, Department for Public Health responded to the comments and amends the administrative regulation as follows:

Page 1
Title of regulation
Line 5
   After “Hemp-derived”, insert “cannabinoid”.
   Delete “cannabidiol”.

Page 1
RELATES TO
Line 6
   After “271.155”, insert “, 260.850”.

Page 1
NECESSITY, FUNCTION, AND CONFORMITY
Lines 16 and 17
   After “utilize hemp-derived”, insert “cannabinoid”.
   Delete “cannabidiol”.
Lines 17 and 18
   After “containing hemp-derived”, insert “cannabinoid”.
   Delete “cannabidiol”.
Line 18
After "for use of hemp-derived", insert "cannabinoid".
Delete "cannabinoid".

Page 1
Section 1(1) – the first one
Line 20
After "Definitions. (1)", insert the following:
"Approved source" means a Kentucky hemp grower, processor, or handler licensed by the Kentucky Department of Agriculture, or an out of state hemp grower, processor, or handler who is duly authorized to produce hemp under the laws of their jurisdiction.
(2)

Page 1
Section 1(1) – the second one
Line 21
Before "(1) "Cannabidiol"", insert "(3) "Cannabinoid"".
Delete "(1) "Cannabidiol" or "CBD"".
After "non-intoxicating", insert "compound".
Delete "cannabinoid".

Page 2
Section 1(2), (3), and (4)
Lines 2, 3, and 4
Renumber these three subsections by inserting "(4)", "(5)", and "(6)", respectively, and by deleting "(2)", "(3)", and "(4)", respectively.

Page 2
Section 1(5)
Line 5
Before "(5)", insert the following:
(7) "Hemp" is defined by KRS 260.850(5).
(8)
Delete "(5)".

Page 2
Section 1(6)
Line 6
Before "(6)", insert "(9)".
Delete "(6)".

Page 2
Section 2(1)
Line 7
After "A person", insert "located in Kentucky".
Page 2
Section 2(1)
Lines 7 and 8
   After “hemp-derived”, delete “CBD”.
   After “ingestible or cosmetic”, insert “cannabinoid”.

Page 2
Section 2(4)
Line 18
   After “hemp-derived”, insert “cannabinoid”.

Page 2
Section 3(1)
Line 20
   After “Each hemp-derived”, insert “cannabinoid”.
   Delete “CBD”.

Page 3
Section 3(2)(b)
Line 4
   After “thirty percent (30%) of the”, insert the following:
   principal display panel of the

Page 3
Section 3(2)(c)
Line 6
   After “hemp-derived”, insert “cannabinoid”.
   Delete “CBD”.

Page 3
Section 3(2)(e)
Line 9
   After “hemp-derived”, insert “cannabinoid”.
   Delete “CBD”.

Page 3
Section 3(2)(f)
Line 11
   After “total amount of”, insert “cannabinoid”.
   Delete “cannabidiol”.

Page 3
Section 3(2)(h)
Line 15
   After the semi-colon, insert “and”.

26
Page 3
Section 3(2)(i) and (j)
Lines 16, 17, and 18
   After "if any", delete "; and" and delete all of paragraph (j) except the final period.

Page 3
Section 3(3)
Line 19
   After "(3)", insert the following:
   An ingestible or cosmetic product that has a total area of twelve (12) square inches or less available to bear labeling shall be labeled in accordance with subsection (2) of this section except the print may be smaller than six (6) point font but shall not measure less than 1/32 of an inch in height.
   (4) The labeling requirements of subsection (2) of this section shall not be printed unduly small in relation to the total area available to bear labeling in order to accommodate unrequired information such as logos, photographic representation of the product, or additional marketing copy.
   (5)
   After "hemp-derived", insert "cannabinoid".
   Delete "CBD".
Lines 19 and 20
   After "product shall!", insert the following:
   Have a tamper evident seal
   Delete the following:
   Bear either a foil seal on the inside or a plastic sealant on the outside

Page 3
Section 3(4)
Line 21
   Before "(4)", insert "(8)".
   Delete "(4)".
   After "hemp-derived", insert "cannabinoid".
   Delete "CBD".

Page 4
Section 4
Line 1
   After "Hemp-derived ingestible", insert "cannabinoid products".
   Delete the following:
   CBD product as a food additive

Page 4
Section 4(1)
Line 1
   After "(1) Hemp-derived", insert "cannabinoid".
   Delete "CBD".
Page 4  
Section 4(2)  
Line 4  
    After "(2)" , insert the following:  
      The hemp-derived cannabinoid shall be obtained from an approved source.  
(3) The food processor or food service establishment shall obtain a valid  
certificate of analysis from the approved source and provide a copy upon  
inspection.  
(4) Food or ingestible product shall not contain a total delta-9  
tetrahydrocannabinol concentration of more than three-tenths of one  
percent (0.3%) on a dry weight basis or contain tetrahydrocannabinol as the  
primary cannabinoid.  
(5)  
    After "hemp-derived", insert "cannabinoid".  
Delete "CBD".  

Page 4  
Section 4(2)(c)  
Line 8  
    After "hemp-derived", insert "cannabinoid".  
· Delete "CBD".