

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(New Administrative Regulation)

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

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

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 cannabidiol 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.

Section 1. Definitions. (1) "Cabinet" is defined by KRS 217.015(3).

(1) "Cannabidiol" or "CBD" means a non-intoxicating cannabinoid found in the hemp plant *Cannabis sativa*.

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

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

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

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

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

Section 2. Permits. (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.

(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 products shall not be manufactured, marketed, sold, or distributed by a home-based processor.

Section 3. Product labeling. (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.

(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 label parallel to the base of the container;

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

(d) The name of the manufacturer or distributor;

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

(f) The total amount of cannabidiol 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";

(i) An expiration date, if any; and

(j) 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.

(4) 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.

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 or prior to retail sale at a food service establishment.

(2) A food service establishment offering hemp-derived 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 CBD product is within the federal legal limit of three-tenths to one percent (0.3%) delta-9 tetrahydrocannabinol.

STEVEN J. STACK, MD, MBA, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 6, 2020

FILED WITH LRC: October 8, 2020 at 2:22 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing,

you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Julie Brooks or Donna Little

(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.

(b) The necessity of this administrative regulation: With the passage of the federal Agriculture Improvement Act of 2018, hemp-derived CBD 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 CBD.

(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 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 CBD 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 offer 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 CBD ingestible and cosmetic prod-

ucts 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 CBD products will pay the fee outlined in 902 KAR 45:180. Those persons seeking to manufacture a hemp-derived CBD cosmetic product will pay the \$150 fee as outlined in 902 KAR 45:180. A retail food service establishment offering hemp-derived CBD as an additive to prepared food will pay the fee outlined 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 CBD 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? Tiering is not applied. The permitting and labeling requirement will impact those seeking to produce ingestible and cosmetic hemp-derived CBD products equally.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

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.

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: