

Substitute for HOUSE BILL No. 2400

By Committee on Federal and State Affairs

2-24

1 AN ACT concerning food products; relating to the Kansas food, drug and
2 cosmetic act; regulating the sale and distribution of kratom products;
3 amending K.S.A. 65-656 and repealing the existing section.
4

5 *Be it enacted by the Legislature of the State of Kansas:*

6 Section 1. K.S.A. 65-656 is hereby amended to read as follows: 65-
7 656. For the purpose of this act:

8 (a) "Secretary" means the secretary of agriculture or the secretary's
9 authorized representatives.

10 (b) "Person" means an individual, partnership, governmental entity,
11 corporation, or association of persons.

12 (c) "Food" means: (1) Articles used for food or drink for humans or
13 other animals; (2) chewing gum; and (3) articles used for components of
14 any such article.

15 (d) "Drug" means: (1) Articles recognized in the official United States
16 pharmacopoeia, official homeopathic pharmacopoeia of the United States,
17 or official national formulary, or any supplement to any of them; (2)
18 articles intended for use in diagnosis, cure, mitigation, treatment or
19 prevention of disease in humans or other animals; (3) articles, other than
20 food, intended to affect the structure or any function of the body of
21 humans or other animals; and (4) articles intended for use as a component
22 of any article specified in paragraph (1), (2), or (3);, but does not include
23 devices or their components, parts or accessories. The term "drug" shall
24 not include amygdalin (laetrile).

25 (e) "Device," except as used in ~~subsection (j) of K.S.A. 65-657(j),~~
26 ~~subsection (f) of K.S.A. 65-665(f), subsections (e) and (o) of K.S.A. 65-~~
27 ~~669(c) and (o), and subsection (e) of K.S.A. 65-671(c),~~ and amendments
28 thereto, means instruments, apparatus and contrivances, including their
29 components, parts and accessories, intended for use in the diagnosis, cure,
30 mitigation, treatment, or prevention of disease in humans or other animals
31 or to affect the structure or any function of the body of humans or other
32 animals.

33 (f) "Cosmetic" means: (1) Articles intended to be rubbed, poured,
34 sprinkled, or sprayed on, introduced into, or otherwise applied to the
35 human body or any part thereof for cleaning, beautifying, promoting
36 attractiveness or altering appearance; and (2) articles intended for use as a

1 component of any such articles, except that such term shall not include
2 soap.

3 (g) "Official compendium" means the official United States
4 pharmacopoeia, official homeopathic pharmacopoeia of the United States,
5 official national formulary or any supplement to any of them.

6 (h) "Label" means a display of written, printed or graphic matter upon
7 the immediate container of any article; and a requirement made by or
8 under authority of this act that any word, statement, or other information
9 appearing on the label shall not be considered to be complied with unless
10 such word, statement, or other information also appears on the outside
11 container or wrapper, if any there be, of the retail package of such article,
12 or is easily legible through the outside container or wrapper.

13 (i) "Immediate container" does not include package liners.

14 (j) "Labeling" means all labels and other written, printed or graphic
15 matter upon an article or any of its containers or wrappers or
16 accompanying such article.

17 (k) "Advertisement" means all representations disseminated in any
18 manner or by any means other than by labeling, for the purpose of
19 inducing, or which are likely to induce, directly or indirectly, the purchase
20 of food, drugs, devices or cosmetics.

21 (l) "New drug" means: (1) Any drug the composition of which is such
22 that such drug is not generally recognized, among experts qualified by
23 scientific training and experience to evaluate the safety and effectiveness
24 of drugs, as safe and effective for use under the conditions prescribed,
25 recommended, or suggested in the labeling thereof; or (2) any drug the
26 composition of which is such that such drug, as a result of investigations to
27 determine its safety and effectiveness for use under such conditions, has
28 become so recognized, but ~~which~~ that has not, otherwise than in such
29 investigations, been used to a material extent or for a material time under
30 such conditions. The term "new drug" shall not include amygdalin
31 (laetrile).

32 (m) "Contaminated with filth" applies to any food, drug, device or
33 cosmetic not securely protected from dust, dirt, and as far as may be
34 necessary by all reasonable means, from all foreign or injurious
35 contaminations.

36 (n) "Pesticide chemical" means any substance ~~which~~ that, alone, in
37 chemical combination, or in formulation with one or more other
38 substances is a "pesticide" within the meaning of the agricultural
39 chemicals act, K.S.A. 2-2202, and amendments thereto, and ~~which~~ that is
40 used in the production, storage or transportation of raw agricultural
41 commodities.

42 (o) "Raw agricultural commodity" means any food in its raw or
43 natural state, including all fruits that are washed, colored, or otherwise

1 treated in their unpeeled natural form prior to marketing.

2 (p) "Food additive" means any substance, the intended use of which
3 results or may be reasonably expected to result, directly or indirectly, in its
4 becoming a component or otherwise affecting the characteristics of any
5 food, including any substance intended for use in producing,
6 manufacturing, packing, processing, preparing, treating, packaging,
7 transporting, or holding food; and including any source of radiation
8 intended for any such use, if such substance is not generally recognized,
9 among experts qualified by scientific training and experience to evaluate
10 its safety, as having been adequately shown through scientific procedures,
11 or, in the case of a substance used in a food prior to January 1, 1958,
12 through either scientific procedures or experience based on common use in
13 food, to be safe under the conditions of its intended use. "Food additive"
14 does not include: (1) A pesticide chemical in or on a raw agricultural
15 commodity; (2) a pesticide chemical to the extent that it is intended for use
16 or is used in the production, storage, or transportation of any raw
17 agricultural commodity; (3) a color additive; or (4) any substance used in
18 accordance with a sanction or approval granted prior to the enactment of
19 the food additive amendment of 1958, pursuant to the federal act.

20 (q) (1) "Color additive" means a material ~~which~~ *that*: (A) Is a dye,
21 pigment, or other substance made by a process of synthesis or similar
22 artifice, or extracted, isolated, or otherwise derived, with or without
23 intermediate or final change of identity from a vegetable, animal, mineral,
24 or other source; or (B) when added or applied to a food, drug or cosmetic,
25 or to the human body or any part thereof, is capable, alone or through
26 reaction with another substance, of imparting color thereto; ~~except that~~
27 ~~such~~. *The term "color additive" does not include any material which that*
28 has been or hereafter is exempted under the federal act.

29 (2) The term "color" includes black, white and intermediate grays.

30 (3) Nothing in this subsection shall be construed to apply to any
31 pesticide chemical, soil or plant nutrient, or other agricultural chemical
32 solely because of its effect in aiding, retarding or otherwise affecting,
33 directly or indirectly, the growth or other natural physiological process of
34 produce of the soil and thereby affecting its color, whether before or after
35 harvest.

36 (r) "Imitation" means any article made in the semblance of another,
37 consisting of similar or dissimilar ingredients and being capable of being
38 substituted for the imitated article without the knowledge of the consumer.

39 (s) "Federal act" means the federal food, drug and cosmetic act, title
40 21 U.S.C. § 301 et seq.;, 52 Stat. 1040 et seq.

41 (t) "Department" means the Kansas department of agriculture.

42 (u) "Distribution" means the provision of food, drug, cosmetic or
43 device to another person and includes selling, offering for sale, giving,

1 supplying, transporting, applying and dispensing.

2 (v) "Food establishment" means any place in which food is prepared,
3 served or offered for sale or service on the premises or elsewhere. "Food
4 establishment" does not include roadside markets that offer only whole
5 fresh fruits, nuts and vegetables for sale. "Food establishment" includes,
6 but is not limited to:

7 (1) Eating or drinking establishments, fixed or mobile restaurants,
8 coffee shops, cafeterias, short-order cafes, luncheonettes, tea rooms, grills,
9 sandwich shops, soda fountains, taverns, private clubs, roadside stands,
10 industrial-feeding establishments, catering kitchens, commissaries and any
11 other private, public or nonprofit organizations routinely serving food; and

12 (2) grocery stores, convenience stores, bakeries and locations where
13 food is provided for the public with or without charge.

14 (w) "Food processing plant" means a commercial operation that
15 processes or stores food for human consumption and provides food for
16 distribution to other business entities at other locations, including other
17 food processing plants and food establishments. "Food processing plant"
18 does not include any operation or individual beekeeper that produces and
19 distributes honey to other business entities if the producer does not process
20 the honey beyond extraction from the comb.

21 (x) "Food vending machine" means any self-service device, ~~which,~~
22 *that* upon payment, dispenses unit servings of food, either in bulk or in
23 packages. Such device shall not necessitate replenishing between each
24 vending operation. "Food vending machine" does not include any vending
25 machine dispensing only canned or bottled soft drinks or prepackaged
26 food that does not require temperature control for safety.

27 (y) "Food vending machine company" means any person in the
28 business of operating and servicing food vending machines.

29 (z) "Location" means a physical address, or absent an address, the
30 geographical area within 300 feet of a food establishment or food
31 processing plant. In the case of a mobile food establishment housed in a
32 trailer, such trailer shall be considered a food establishment with its own
33 location. In the case of a mobile food establishment that is not housed in a
34 trailer, the equipment used for storage, preparation or offering of food shall
35 be considered a food establishment with its own location.

36 (aa) "Municipality" means any city or county of this state.

37 (bb) "Processing" means the handling of a food, drug, cosmetic or
38 device, including the production, manufacturing, packaging, packing and
39 labeling of such item.

40 (cc) "Sample" means a small quantity of food and does not include a
41 meal or entree.

42 (dd) "Storage" means holding for distribution or processing.

43 (ee) "*Kratom dealer*" means a person that manufactures, sells,

1 *prepares, produces, distributes or maintains kratom products, or*
2 *advertises or represents that such person manufactures, sells, prepares,*
3 *produces, distributes or maintains kratom products, including, but not*
4 *limited to, a manufacturer, wholesaler, retail store, restaurant, hotel,*
5 *catering facility, camp, bakery, delicatessen, grocery store, convenience*
6 *store or nursing home.*

7 *(ff) "Kratom product" means a food containing any part of the plant*
8 *mitragyna speciosa.*

9 New Sec. 2. The provisions of sections 2 through 10, and
10 amendments thereto, shall be a part of and supplemental to the Kansas
11 food, drug and cosmetic act.

12 New Sec. 3. (a) The secretary shall adopt rules and regulations
13 establishing fees for the issuance of annual kratom dealer licenses and for
14 other necessary expenses to defray the cost of implementing and enforcing
15 the provisions of this act.

16 (b) All moneys received as fees pursuant to this section shall be
17 remitted to the state treasurer at least monthly. Upon receipt of each such
18 remittance, the state treasurer shall deposit the entire amount in the state
19 treasury to the credit of the food safety fee fund. All expenditures from the
20 food safety fee fund shall be made in accordance with appropriation acts
21 upon warrants of the director of accounts and reports issued pursuant to
22 vouchers approved by the secretary or the secretary's designee.

23 New Sec. 4. (a) Applications for kratom dealer licenses shall be made
24 in such form and manner as prescribed by the secretary and shall be
25 accompanied by the required application and license fees.

26 (b) Each kratom dealer license application that involves the retail sale
27 or wholesale distribution of kratom products, but that does not include the
28 production, manufacture, packaging or labeling of kratom products, shall
29 be approved upon submission of a complete application and timely
30 payment of the prescribed fees.

31 (c) Each kratom dealer application that involves the production,
32 manufacture, packaging or labeling of kratom products shall be approved
33 by the secretary upon submission of a complete application, timely
34 payment of the prescribed fees and completion of a successful inspection
35 of the premises described in the application.

36 (d) A kratom dealer license issued under this act shall apply only to
37 the premises described in the application and in the license issued thereon,
38 and only one location shall be described in each license. A kratom dealer
39 license shall be in addition to any other license, permit or registration
40 required under the Kansas food, drug and cosmetic act, or under any other
41 state or federal law.

42 (e) Every kratom dealer license shall be displayed conspicuously in
43 the licensed premises for which it is issued, and no such license shall be

1 transferable to any other person or location. Whenever any such license is
2 lost, destroyed or mutilated, a duplicate license shall be issued to any
3 otherwise qualified licensee upon application therefor and the payment of
4 a fee in the amount of \$5.

5 (f) Except as otherwise provided in this section, a kratom dealer
6 license shall expire on March 31 following the date of issuance. Licenses
7 may be renewed by applying to the secretary on or before the expiration
8 date. An application for renewal of a license shall be made in such form
9 and manner as prescribed by the secretary and shall be accompanied by the
10 required application and license fees.

11 (g) If the secretary denies the issuance or renewal of any license, the
12 secretary shall give written notice thereof to the licensee. Such written
13 notice shall specify the changes necessary for complete compliance with
14 the provisions of this act and all rules and regulations adopted thereunder,
15 and the secretary shall state that if compliance is achieved within the time
16 designated in such notice, then the license shall be issued or renewed. If
17 the licensee fails to achieve complete compliance within the prescribed
18 time period, the secretary, after notice and an opportunity for a hearing in
19 accordance with the Kansas administrative procedure act, shall deny the
20 application for such license, or the renewal thereof.

21 New Sec. 5. (a) The secretary shall inspect or cause to be inspected
22 the premises of every licensed kratom dealer. If upon inspection, the
23 secretary determines that such licensed premises does not comply with the
24 provisions of this act or the rules and regulations adopted thereunder, the
25 secretary shall give written or electronic notice to the owner, proprietor or
26 agent in charge of such licensed premises and may allow for correction
27 within 10 days or provide for any other civil remedy established by this act
28 and rules and regulations adopted thereunder.

29 (b) The secretary shall have access at all reasonable hours to any
30 location in which kratom products are manufactured, sold, prepared,
31 produced, distributed, maintained or advertised, and to enter any vehicle
32 being used to transport or hold kratom products in commerce for the
33 following purposes:

34 (1) To inspect any location, products or equipment subject to the
35 provisions of this act and rules and regulations adopted thereunder;

36 (2) to inspect or sample any kratom product reported to be
37 adulterated, misbranded or a threat to public health;

38 (3) to inspect or investigate complaints of violations of the provisions
39 of this act and rules and regulations adopted thereunder;

40 (4) to inspect the records concerning the place of origin or the sale of
41 any kratom product;

42 (5) to open any package containing or suspected of containing any
43 kratom product that is exposed or offered for sale; and

1 (6) to take samples of the contents of any kratom product for
2 examination.

3 (c) If the secretary is denied access to any location where such access
4 is sought for the purposes provided in subsections (a) and (b), the secretary
5 may apply to any court of competent jurisdiction for a search warrant
6 authorizing access to such location for such purpose. Upon such
7 application and a showing of cause therefor, the court shall issue such
8 search warrant.

9 New Sec. 6. (a) The secretary, or a duly authorized representative of
10 the secretary, shall inspect and sample kratom products at such time and in
11 such places and to such extent as the secretary or such authorized
12 representative of the secretary considers advisable. The secretary, or a duly
13 authorized representative of the secretary, may stop further sale or
14 movement of any kratom products found to be in violation of any of the
15 provisions of this act, any rules and regulations adopted thereunder or any
16 orders issued thereunder. It shall be the duty of the secretary, or a duly
17 authorized representative of the secretary, to:

18 (1) Enforce and administer the provisions of this act; and

19 (2) sample, inspect, make analysis of and test kratom products
20 transported, sold, offered for sale or exposed for sale within the state at
21 such time and place and to such extent as considered necessary by the
22 secretary to determine whether such kratom products are in compliance
23 with the provisions of this act and rules and regulations adopted
24 thereunder.

25 (b) (1) In addition to any action taken pursuant to K.S.A. 65-660, and
26 amendments thereto, the secretary may issue and enforce a written or
27 printed "stop sale" order to the owner or custodian of any kratom product
28 that the secretary, or a duly authorized representative of the secretary,
29 determines to be in violation of any of the provisions of this act or any
30 rules and regulations adopted thereunder.

31 (2) Except as otherwise approved by the secretary, any "stop sale"
32 order shall prohibit further sale, processing and movement of the kratom
33 product that is subject to such order until the secretary is provided
34 evidence of compliance with the provisions of this act or rules and
35 regulations adopted thereunder and a release from the "stop sale" order of
36 such kratom product is issued.

37 (c) (1) If the secretary finds that the public health or safety is
38 endangered by the continued operation of a kratom dealer, the secretary
39 may temporarily suspend the license of such kratom dealer or order the
40 temporary closure of such kratom dealer's licensed premises without notice
41 or hearing in accordance with the emergency provisions of the Kansas
42 administrative procedure act.

43 (2) A temporary suspension of a license or temporary closure order

1 issued under this section shall not be effective for more than 90 days.
2 Upon the expiration of any such suspension or order, the licensee shall be
3 reinstated to full licensure or allowed to reopen unless the secretary has
4 denied, suspended or revoked such licensee's kratom dealer license,
5 obtained an injunction against such licensee or the license has expired as
6 otherwise provided under section 4, and amendments thereto, or any rules
7 and regulations or orders issued thereunder.

8 (d) The secretary, after providing notice and opportunity for a hearing
9 in accordance with the provisions of the Kansas administrative procedure
10 act, may deny, suspend, modify, revoke or refuse to renew any license if
11 the secretary determines that such applicant or licensee has:

12 (1) Been convicted of or pleaded guilty to a criminal violation of any
13 provision of section 8, and amendments thereto, or any other provision of
14 the Kansas food, drug and cosmetic act;

15 (2) failed to comply with any provision or requirement of this act or
16 any rules and regulations or orders adopted or issued thereunder;

17 (4) interfered with the secretary's ability to carry out inspections or
18 the administration of this act or any rules and regulations adopted
19 thereunder; or

20 (5) denied the secretary access to any premises required to be
21 inspected under the provisions of this act or any rules and regulations
22 adopted thereunder.

23 New Sec. 7. (a) In addition to any other corrective actions ordered,
24 the secretary, after providing notice and an opportunity for a hearing in
25 accordance with provisions of the Kansas administrative procedure act,
26 may impose a civil penalty in an amount not to exceed \$1,000 per
27 violation of this act or any rules and regulations or orders adopted or
28 issued thereunder. In the case of a continuing violation, each day such
29 violation continues shall be deemed a separate violation. Such civil penalty
30 may be assessed in addition to any other penalty provided by law.

31 (b) Any person aggrieved by an order of the secretary as provided in
32 subsection (a) may appeal such order to the district court in the manner
33 provided by the Kansas judicial review act.

34 (c) Any penalty recovered pursuant to the provisions of subsection (a)
35 shall be remitted to the state treasurer in accordance with the provisions of
36 K.S.A. 75-4215, and amendments thereto. Upon receipt of each such
37 remittance, the state treasurer shall deposit the entire amount in the state
38 treasury to the credit of the compliance education fee fund of the
39 department of agriculture.

40 New Sec. 8. (a) It shall be unlawful for any person to manufacture,
41 sell, prepare, produce, distribute, maintain, advertise or represent that such
42 person manufactures, sells, prepares, produces, distributes, maintains or
43 advertises kratom products without a license issued pursuant to this act.

1 (b) It shall be unlawful for any kratom dealer to manufacture, sell,
2 prepare, produce, distribute, sell or otherwise provide any kratom product
3 that is adulterated as described in K.S.A. 65-664, and amendments thereto.

4 (c) In addition to any adulteration as described in K.S.A. 65-664, and
5 amendments thereto, kratom products shall also be considered adulterated
6 if such products contain:

7 (1) A level of 7-hydroxymitragynine in the alkaloid fraction that is
8 greater than 2% of the alkaloid composition of such product; or

9 (2) any synthetic alkaloids including synthetic mitragynine, synthetic
10 7-hydroxymitragynine or any other synthetically derived compounds of
11 the kratom plant.

12 (d) It shall be unlawful for any kratom dealer to manufacture, sell,
13 prepare, produce, distribute, or otherwise provide any kratom product that
14 is misbranded as described in K.S.A. 65-665, and amendments thereto. A
15 kratom product shall be deemed misbranded if the label does not state the
16 amount of mitragynine and 7-hydroxymitragynine contained in such
17 product.

18 (e) It shall be unlawful for any kratom dealer to distribute, sell or
19 otherwise provide any kratom product to an individual under 18 years of
20 age.

21 (f) Violation of this section is a class C misdemeanor.

22 New Sec. 9. An advertisement for a kratom product shall be deemed
23 a false claim if the advertisement is false or misleading in any particular
24 aspect of such product, including, but not limited to, representing such
25 kratom product to have unproven medical or health benefits.

26 New Sec. 10. The secretary shall adopt rules and regulations for the
27 administration and enforcement of sections 2 through 9, and amendments
28 thereto, including, but not limited to, the format, size and placement of
29 labels, and the information required to be included on such labels, all fees
30 necessary for carrying out the provisions of sections 2 through 9, and
31 amendments thereto, all safety and sanitary standards required and any
32 other provisions necessary to effectuate this act.

33 Sec. 11. K.S.A. 65-656 is hereby repealed.

34 Sec. 12. This act shall take effect and be in force from and after its
35 publication in the statute book.