

HOUSE BILL No. 2056

By Committee on Federal and State Affairs

1-13

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) (1) "Drug" means:

16 ~~(1)~~(A) Articles recognized in the official United States
17 pharmacopoeia, official homeopathic pharmacopoeia of the United States,
18 or official national formulary, or any supplement to any of them;

19 ~~(2)~~(B) articles intended for use in diagnosis, cure, mitigation,
20 treatment or prevention of disease in humans or other animals;

21 ~~(3)~~(C) articles, other than food, intended to affect the structure or any
22 function of the body of humans or other animals; and

23 ~~(4)~~(D) articles intended for use as a component of any article
24 specified in ~~paragraph (1), (2), or (3); but does not include devices or their~~
25 ~~components, parts or accessories~~ subparagraph (A), (B) or (C).

26 (2) The term "drug" shall not include:

27 (A) *Devices or their components, parts or accessories; or*

28 (B) amygdalin (laetrile).

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

1 (f) "Cosmetic" means: (1) Articles intended to be rubbed, poured,
2 sprinkled, or sprayed on, introduced into, or otherwise applied to the
3 human body or any part thereof for cleaning, beautifying, promoting
4 attractiveness or altering appearance; and (2) articles intended for use as a
5 component of any such articles, except that such term shall not include
6 soap.

7 (g) "Official compendium" means the official United States
8 pharmacopoeia, official homeopathic pharmacopoeia of the United States,
9 official national formulary or any supplement to any of them.

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

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

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

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

25 (1) (1) "New drug" means:

26 ~~(1)~~(A) Any drug the composition of which is such that such drug is
27 not generally recognized, among experts qualified by scientific training
28 and experience to evaluate the safety and effectiveness of drugs, as safe
29 and effective for use under the conditions prescribed, recommended, or
30 suggested in the labeling thereof; or

31 ~~(2)~~(B) any drug the composition of which is such that such drug, as
32 a result of investigations to determine its safety and effectiveness for use
33 under such conditions, has become so recognized, but ~~which~~ that has not,
34 otherwise than in such investigations, been used to a material extent or for
35 a material time under such conditions.

36 (2) The term "new drug" shall not include amygdalin (laetrile).

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

41 (n) "Pesticide chemical" means any substance ~~which~~ that, alone, in
42 chemical combination, or in formulation with one or more other
43 substances is a "pesticide" within the meaning of the agricultural

1 chemicals act, K.S.A. 2-2202, and amendments thereto, and ~~which that~~
 2 used in the production, storage or transportation of raw agricultural
 3 commodities.

4 (o) "Raw agricultural commodity" means any food in its raw or
 5 natural state, including all fruits that are washed, colored, or otherwise
 6 treated in their unpeeled natural form prior to marketing.

7 (p) (1) "Food additive" means any substance, the intended use of
 8 which results or may be reasonably expected to result, directly or
 9 indirectly, in its becoming a component or otherwise affecting the
 10 characteristics of any food, including any substance intended for use in
 11 producing, manufacturing, packing, processing, preparing, treating,
 12 packaging, transporting, or holding food; and including any source of
 13 radiation intended for any such use, if such substance is not generally
 14 recognized, among experts qualified by scientific training and experience
 15 to evaluate its safety, as having been adequately shown through scientific
 16 procedures, or, in the case of a substance used in a food prior to January 1,
 17 1958, through either scientific procedures or experience based on common
 18 use in food, to be safe under the conditions of its intended use.

19 (2) "Food additive" does not include:

20 ~~(1)~~(A) A pesticide chemical in or on a raw agricultural commodity;

21 ~~(2)~~(B) a pesticide chemical to the extent that it is intended for use or
 22 is used in the production, storage, or transportation of any raw agricultural
 23 commodity;

24 ~~(3)~~(C) a color additive; or

25 ~~(4)~~(D) any substance used in accordance with a sanction or approval
 26 granted prior to the enactment of the food additive amendment of 1958,
 27 pursuant to the federal act.

28 (q) (1) "Color additive" means a material ~~which that~~:

29 (A) Is a dye, pigment, or other substance made by a process of
 30 synthesis or similar artifice, or extracted, isolated, or otherwise derived,
 31 with or without intermediate or final change of identity from a vegetable,
 32 animal, mineral, or other source; or

33 (B) when added or applied to a food, drug or cosmetic, or to the
 34 human body or any part thereof, is capable, alone or through reaction with
 35 another substance, of imparting color thereto; ~~except that such term.~~

36 (2) *The term "color additive" does not include any material ~~which~~*
 37 *that has been or hereafter is exempted under the federal act.*

38 ~~(2)~~(3) The term "color" includes black, white and intermediate grays.

39 ~~(3)~~(4) Nothing in this subsection shall be construed to apply to any
 40 pesticide chemical, soil or plant nutrient, or other agricultural chemical
 41 solely because of its effect in aiding, retarding or otherwise affecting,
 42 directly or indirectly, the growth or other natural physiological process of
 43 produce of the soil and thereby affecting its color, whether before or after

1 harvest.

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

5 (s) "Federal act" means the federal food, drug and cosmetic act, title
6 21 U.S.C. § 301 et seq.; 52 Stat. 1040 et seq.

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

8 (u) "Distribution" means the provision of food, drug, cosmetic or
9 device to another person and includes selling, offering for sale, giving,
10 supplying, transporting, applying and dispensing.

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

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

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

23 (w) "Food processing plant" means a commercial operation that
24 processes or stores food for human consumption and provides food for
25 distribution to other business entities at other locations, including other
26 food processing plants and food establishments. "Food processing plant"
27 does not include any operation or individual beekeeper that produces and
28 distributes honey to other business entities if the producer does not process
29 the honey beyond extraction from the comb.

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

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

38 (z) "Location" means a physical address, or absent an address, the
39 geographical area within 300 feet of a food establishment or food
40 processing plant. In the case of a mobile food establishment housed in a
41 trailer, such trailer shall be considered a food establishment with its own
42 location. In the case of a mobile food establishment that is not housed in a
43 trailer, the equipment used for storage, preparation or offering of food shall

1 be considered a food establishment with its own location.

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

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

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

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

9 (ee) "*Kratom dealer*" means a person that manufactures, sells,
10 prepares, produces, distributes or maintains kratom products, or
11 advertises or represents that such person manufactures, sells, prepares,
12 produces, distributes or maintains kratom products, including, but not
13 limited to, a manufacturer; wholesaler; retail store, restaurant, hotel,
14 catering facility, camp, bakery, delicatessen, grocery store, convenience
15 store or nursing home.

16 (ff) "*Kratom product*" means a food containing any part of the
17 *plantmitragyna speciosa*.

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

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

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

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

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

40 (c) Each kratom dealer application that involves the production,
41 manufacture, packaging or labeling of kratom products shall be approved
42 by the secretary upon submission of a complete application, timely
43 payment of the prescribed fees and completion of a successful inspection

1 of the premises described in the application.

2 (d) A kratom dealer license issued under this act shall apply only to
3 the premises described in the application and in the license issued thereon,
4 and only one location shall be described in each license. A kratom dealer
5 license shall be in addition to any other license, permit or registration
6 required under the Kansas food, drug and cosmetic act, or under any other
7 state or federal law.

8 (e) Every kratom dealer license shall be displayed conspicuously in
9 the licensed premises for which it is issued, and no such license shall be
10 transferable to any other person or location. Whenever any such license is
11 lost, destroyed or mutilated, a duplicate license shall be issued to any
12 otherwise qualified licensee upon application therefor and the payment of
13 a fee in the amount of \$5.

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

20 (g) If the secretary denies the issuance or renewal of any license, the
21 secretary shall give written notice thereof to the licensee. Such written
22 notice shall specify the changes necessary for complete compliance with
23 the provisions of this act and all rules and regulations adopted thereunder,
24 and the secretary shall state that if compliance is achieved within the time
25 designated in such notice, then the license shall be issued or renewed. If
26 the licensee fails to achieve complete compliance within the prescribed
27 time period, the secretary, after notice and an opportunity for a hearing in
28 accordance with the Kansas administrative procedure act, shall deny the
29 application for such license, or the renewal thereof.

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

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

43 (1) To inspect any location, products or equipment subject to the

1 provisions of this act and rules and regulations adopted thereunder;

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

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

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

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

10 (6) to take samples of the contents of any kratom product for
11 examination.

12 (c) If the secretary is denied access to any location where such access
13 is sought for the purposes provided in subsections (a) and (b), the secretary
14 may apply to any court of competent jurisdiction for a search warrant
15 authorizing access to such location for such purpose. Upon such
16 application and a showing of cause therefor, the court shall issue such
17 search warrant.

18 New Sec. 6. (a) The secretary, or a duly authorized representative of
19 the secretary, shall inspect and sample kratom products at such time and in
20 such places and to such extent as the secretary or such authorized
21 representative of the secretary considers advisable. The secretary, or a duly
22 authorized representative of the secretary, may stop further sale or
23 movement of any kratom products found to be in violation of any of the
24 provisions of this act, any rules and regulations adopted thereunder or any
25 orders issued thereunder. It shall be the duty of the secretary, or a duly
26 authorized representative of the secretary, to:

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

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

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

40 (2) Except as otherwise approved by the secretary, any "stop sale"
41 order shall prohibit further sale, processing and movement of the kratom
42 product that is subject to such order until the secretary is provided
43 evidence of compliance with the provisions of this act or rules and

1 regulations adopted thereunder and a release from the "stop sale" order of
2 such kratom product is issued.

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

9 (2) A temporary suspension of a license or temporary closure order
10 issued under this section shall not be effective for more than 90 days.
11 Upon the expiration of any such suspension or order, the licensee shall be
12 reinstated to full licensure or allowed to reopen unless the secretary has
13 denied, suspended or revoked such licensee's kratom dealer license,
14 obtained an injunction against such licensee or the license has expired as
15 otherwise provided under section 4, and amendments thereto, or any rules
16 and regulations or orders issued thereunder.

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

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

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

26 (3) interfered with the secretary's ability to carry out inspections or
27 the administration of this act or any rules and regulations adopted
28 thereunder; or

29 (4) denied the secretary access to any premises required to be
30 inspected under the provisions of this act or any rules and regulations
31 adopted thereunder.

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

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

43 (c) Any penalty recovered pursuant to the provisions of subsection (a)

1 shall be remitted to the state treasurer in accordance with the provisions of
2 K.S.A. 75-4215, and amendments thereto. Upon receipt of each such
3 remittance, the state treasurer shall deposit the entire amount in the state
4 treasury to the credit of the compliance education fee fund of the
5 department of agriculture.

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

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

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

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

19 (2) any synthetic alkaloids including synthetic mitragynine, synthetic
20 7-hydroxymitragynine or any other synthetically derived compounds of
21 the kratom plant.

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

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

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

32 New Sec. 9. An advertisement for a kratom product shall be deemed
33 a false claim if the advertisement is false or misleading in any particular
34 aspect of such product, including, but not limited to, any claims not
35 authorized by the federal food and drug administration or the secretary.

36 New Sec. 10. The secretary shall adopt rules and regulations for the
37 administration and enforcement of sections 2 through 9, and amendments
38 thereto, including, but not limited to, the format, size and placement of
39 labels, and the information required to be included on such labels, all fees
40 necessary for carrying out the provisions of sections 2 through 9, and
41 amendments thereto, all safety and sanitary standards required and any
42 other provisions necessary to effectuate this act.

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

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