

HOUSE BILL NO. 407

INTRODUCED BY N. NICOL

A BILL FOR AN ACT ENTITLED: "AN ACT CREATING THE KRATOM CONSUMER PROTECTION ACT;
PROVIDING DEFINITIONS; PROVIDING KRATOM PRODUCT LIMITATIONS; PROVIDING FOR KRATOM
PRODUCT REGISTRATION; PROVIDING FOR KRATOM PROCESSOR, DISTRIBUTOR, AND RETAILER
REGISTRATION; PROVIDING FOR LABELING REQUIREMENTS; PROVIDING FOR ENFORCEMENT BY
THE DEPARTMENT OF REVENUE; PROVIDING CIVIL PENALTIES; PROVIDING FOR MISDEMEANOR
AND FELONY CONVICTIONS; PROVIDING FOR FEES AND TAXES; PROVIDING RULEMAKING
AUTHORITY; ~~AND PROVIDING FOR CONTINGENT FEDERAL PREEMPTION~~ PROVIDING A STATUTORY
APPROPRIATION; AMENDING SECTION 17-7-502, MCA; AND PROVIDING A DELAYED EFFECTIVE
DATE."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

(Refer to Introduced Bill)

Strike everything after the enacting clause and insert:

NEW SECTION. **Section 1. Short title -- purpose.** (1) [Sections 1 through 7] may be cited as the
"Kratom Consumer Protection Act".

(2) It is the purpose of [sections 1 through 7] to prohibit the selling, giving, or other distribution of
kratom products to the public unless specifically authorized by [sections 1 through 7] or other statutory act of
the legislature. It is the express purpose of [sections 1 through 7] to prohibit the sale of kratom products to
persons under 21 years of age.

NEW SECTION. **Section 2. Definitions.** As used in [sections 1 through 7], unless context requires
otherwise, the following definitions apply:

(1) "Attractive to children" means kratom products manufactured in the shape of cartoons or

animals or manufactured or packaged in a form that bears any reasonable resemblance to an existing candy product that is familiar to the public as a widely distributed, branded food product so that a product could be mistaken for the branded product, especially by children.

(2) "Department" means the department of revenue.

(3) "Kratom" means the plant *Mitragyna speciosa* or any part of that plant.

(4) "Kratom distributor" means a person importing into or purchasing in Montana kratom products for sale or resale to kratom retailers registered in Montana.

(5) "Kratom extract" means a substance or compound obtained by extraction of the *Mitragyna speciosa* leaf that is intended for ingestion and contains more than trace amounts of *Mitragyna speciosa* and contains other alkaloids of the kratom plant, and which does not contain any controlled substances or levels of residual solvents higher than is allowed in the United States Pharmacopeia 467.

(6) "Kratom processor" means a person who manufactures or produces kratom products.

(7) "Kratom product" means a finished article containing any part of a leaf of the plant *Mitragyna speciosa* in fresh, dehydrated, or dried form, or a kratom extract, including kratom beverages prepared and sold in food establishments.

(8) "Kratom retailer" means a person that sells or otherwise provides kratom products to the public.

(9) "Production batch" means a quantity of kratom product for individual use from a processed lot.

(10) "Synthesized material" means an alkaloid, metabolite, or alkaloid derivative that has been created by chemical synthesis or biosynthetic means, including but not limited to fermentation, recombinant techniques, or yeast-derived, enzymatic techniques, rather than traditional food preparation techniques, such as heating or extracting, that synthetically alters the composition of any kratom alkaloid or constituent.

NEW SECTION. Section 3. Kratom product restrictions. A kratom processor may not prepare, distribute, sell, or expose for sale a kratom product that:

(1) contains a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the alkaloid composition of the kratom product;

(2) contains synthesized material;

(3) contains or is adulterated with a dangerous non-kratom substance if it contains a poisonous or

1 otherwise deleterious non-kratom ingredient, including but not limited to the substances listed as a controlled
2 substances under state or federal law;
3 (4) are combustible, intended to be used for vaporization, or injectable;
4 (5) are manufactured in a manner that is attractive to children;
5 (6) does not have proof of appropriate quality testing for each production batch from an ISO 17025
6 laboratory in the form of a certificate of analysis representing that:
7 (a) the kratom product does not contain levels of residual solvents, biological contaminants, or
8 heavy metal contaminants that meet the standard for dietary supplement products; and
9 (b) the production batch as defined in [section 2] meets concentration and content limits; or
10 (7) contains levels of residual solvents higher than is allowed in [section 2(5)].
11

12 **NEW SECTION. Section 4. Kratom product and entity registration -- fees -- tax.**(1) Kratom
13 processors, kratom distributors, and kratom retailers must register annually with the department.

14 (2) A kratom processor may not prepare, distribute, sell, or offer for sale a kratom product that is
15 not registered with the department.

16 (3) (a) The kratom processor responsible for placing a kratom product into commerce in the state
17 shall register with the department annually to offer for sale kratom products manufactured in an approved
18 kratom delivery form and pay a \$500 fee.

19 (4) The registration must include the following sworn certifications from the kratom processor:

20 (a) the kratom product being registered meets all of the requirements in [section 3] and this
21 section;

22 (b) a certification from a qualified independent auditor that the registrant meets or exceeds
23 guidelines published by the United States food and drug administration for current good manufacturing
24 practices for any facility that manufactures, processes, packs, or holds a kratom product;

25 (c) a current United States food and drug administration food facility registration certificate or a
26 certification from the local authority where the manufacturing physically takes place that the facility is registered
27 as a food facility for any processor's facility that manufactures, processes, packs, or holds a kratom product;

28 (d) a statement that the processor has a reasonable basis that the kratom product is safe for

consumption under the conditions of use set forth on the label. The registrant assumes responsibility and liability for the kratom products offered for sale.

(e) the submission of a certificate of analysis from a certified independent third-party laboratory showing compliance with the requirements of [sections 1 through 7] for residual solvents, 7-hydroxymitragynine content, and heavy metal contaminants.

(5) An entity must annually renew its registration or the registration will lapse automatically. An entity with a lapsed registration must reregister with the department and may not sell kratom products until the entity has reregistered with the department.

(6) A product that contains the same kratom ingredients in the same kratom delivery form, but a different container, package, or volume, must be included in a single registration.

(7) A kratom distributor who distributes kratom products in the state shall register with the department annually and pay a \$400 fee.

(8) A kratom retailer who sells kratom products to the public in the state shall register with the department annually and pay a \$400 fee.

(9) The department shall publish and maintain a kratom registration page on its official website listing all currently registered kratom products for sale by kratom retailers that allows retailers to verify registered kratom products they are permitted to sell to consumers.

(10) Kratom products that are prepared and served fresh by a food service establishment are regulated under [sections 1 through 7] but are exempt from registration and retail product labeling requirements as provided in [section 5(3)].

(11) If the department determines a kratom product registration fails to meet the requirements for registration, the kratom processor may seek a review, and the department shall require the payment of all estimated costs associated with the review from the kratom processor prior to the commencement of the review.

(12) There is a 5% excise tax on the wholesale selling price of all kratom products. The tax imposed pursuant to this subsection on a kratom distributor is due at the end of a quarter from the kratom distributor on kratom sold by the kratom distributor during the quarter. The tax is payable to the department and must be deposited into the department's fund as provided in [section 7].

- 1
- 2 NEW SECTION. Section 5. Labeling. (1) A kratom product produced, manufactured, distributed,
- 3 offered, sold, or offered for sale must have a label that clearly and conspicuously provides all of the following
- 4 information on each retail package:
- 5 (a) a statement against the use by individuals who are under 21 years of age or who are pregnant
- 6 or breastfeeding;
- 7 (b) a recommendation to consult a health care professional prior to use;
- 8 (c) a statement that kratom may be habit forming;
- 9 (d) the following statement: "These statements have not been evaluated by the United States Food
- 10 and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.";
- 11 (e) the name and the address for the place of business of the registrant; and
- 12 (f) directions for use that include the following:
- 13 (i) a recommended amount of the kratom product per serving that is:
- 14 (A) for product forms such as capsules, gummies, prepackaged single serving units, and similar
- 15 product forms, clearly described on the label; or
- 16 (B) for beverages, liquids, or loose powders, a clear instruction or a mark on the package or
- 17 container that clearly informs the consumer on the recommended serving size.
- 18 (ii) a recommended number of servings that can be safely consumed in a 24-hour period;
- 19 (iii) a listing of the servings per container; and
- 20 (iv) a listing of kratom alkaloids and other ingredients in the product, including quantitative not-to-
- 21 exceed declarations of the amount per serving of each of the following:
- 22 (A) mitragynine; and
- 23 (B) 7-hydroxymitragynine.
- 24 (2) The department shall approve labels for kratom products once by kratom processors. If a
- 25 kratom processor changes a kratom product, the department shall withdraw approval and the kratom processor
- 26 must seek reapproval of the kratom product. The department may charge a fee in connection with the
- 27 reapproval.
- 28 (3) (a) This section does not apply to kratom products that are prepared and served fresh by a

1 food service establishment, including but not limited to kratom tea houses that brew tea for consumption on the
2 premises. Entities that prepare and serve fresh kratom products that are served fresh by a food service
3 establishment shall purchase directly from the kratom distributor and are not subject to labeling and product
4 registration requirements.

5 (b) A food service establishment under Title 50, chapter 31, may prepare and serve fresh kratom
6 products if it is a licensed kratom retailer under [sections 1 through 7].

7
8 **NEW SECTION. Section 6. Department -- enforcement.** (1) Kratom processors, kratom distributors,
9 and kratom retailers are prohibited from selling any kratom product that does not have a current registration
10 with the department. A kratom processor may only sell products to a kratom distributor. A kratom distributor
11 may only sell kratom products to a kratom retailer.

12 (2) Processors, distributors, and retailers of kratom products are subject to the following penalties:

13 (a) a fine of \$10,000 on the processor, distributor, or retailer for the sale of each unregistered
14 product or for sales to persons under 21 years of age;

15 (b) a fine of \$15,000 on the processor, distributor, or the retailer for a second violation of the sale
16 of the same unregistered product or for sales to persons under 21 years of age; or

17 (c) for a third violation for the sale of an unregistered product or the sale to a person under 21
18 years of age, the processor, distributor, or retailer must be prohibited from the sale of any kratom product in the
19 state for a period of 2 years.

20 (3) Kratom products that are intended for human ingestion may not be sold in this state to a person
21 who is under 21 years of age.

22 (4) A person who purposely or knowingly violates [sections 1 through 7] commits a misdemeanor,
23 punishable as provided under Title 45.

24 (5) A person who purposely or knowingly commits a second or subsequent violation of [sections 1
25 through 7] within 1 year after the initial violation commits a misdemeanor, punishable as provided in Title 45.

26 (6) A registrant that purposely or knowingly manufactures, delivers, holds, offers for sale,
27 distributes, or sells a kratom product that contains any controlled substance listed in state or federal law is guilty
28 of a felony as provided in in Title 45.

(7) A registrant that purposely or knowingly manufactures, delivers, holds, offers for sale, distributes, or sells a kratom product that contains synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compound of the plant *Mitragyna speciosa* commits a misdemeanor, punishable as provided in Title 45.

(8) Upon receipt of a violation report on any kratom product offered for sale, the department shall require the registrant to produce an updated and current certificate of analysis in a reasonable timeframe from a certified independent third-party laboratory showing compliance with the requirements of [sections 1 through 7] for safe kratom products. If the registrant does not provide the certificate of analysis and copies of all product labels in the specified timeframe, the registration for that kratom product must be revoked and a stop sale order must be issued for products covered by this registration.

(9) If the department has a reasonable basis to require an independent third-party test of a registered kratom product by a laboratory of the department's choice, the registrant must be required to submit payment for the test within a reasonable timeframe. If the registrant does not tender payment to the department within 30 days of receipt of the invoice for the testing, the department shall revoke the registration for that kratom product and a stop sale order will be issued for products covered by this registration.

(10) The department may seize or destroy any kratom product that does not comply with the requirements of [sections 1 through 7]. The department may act on any complaint and has the authority to reasonably inspect the books and records of any entity required to register under [sections 1 through 7].

(11) A retailer does not violate this section if it is shown by a preponderance of the evidence that the retailer relied in good faith upon the representations of a manufacturer, processor, packer, or distributor of food represented to be a kratom product.

(12) Department proceedings under [sections 1 through 7] are subject to the Montana Administrative Procedure Act, Title 2, chapter 4.

NEW SECTION. Section 7. Rulemaking -- department fund. (1) The department shall adopt rules to administer provisions of [sections 1 through 7]. The rules must provide for:

(a) the process for a registration of a kratom product by a kratom processor;

(b) the process for registration of a kratom processor, kratom distributor, or kratom retailer under

[section 4];

(c) the requirements for enforcing the restriction on the sale of any kratom product to a person under 21 years of age;

(d) any fees or information required for registration as provided in [section 4], including but not limited to information required, contact information, and certifications from qualified independent auditors;

(e) any taxes collected pursuant to [sections 1 through 7];

(f) the requirements of payment of any fees to the department associated with enforcement on any noncompliant or nonregistered kratom products;

(g) proof of appropriate quality testing as provided in [section 3];

(h) procedures for electronic applications for registration and payments of fees or taxes;

(i) the department's website listing products and entities registered under [sections 1 through 7];
and

(j) anything deemed reasonably necessary to administer [sections 1 through 7].

(2) (a) There is a dedicated kratom state special revenue account within the state special revenue fund established in 17-2-102, to be administered by the department.

(b) The account consists of:

(i) money deposited into the account pursuant to [sections 1 through 7];

(ii) the taxes collected pursuant to [section 4];

(iii) license fees deposited into the account pursuant to [section 4]; and

(iv) civil penalties collected under [sections 1 through 7].

(c) Except as provided in subsection (2)(d), money in the account is statutorily appropriated, as provided in 17-7-502, to the department and may be used only for the purposes of this administering [sections 1 through 7].

(d) At the end of each fiscal year, the department shall transfer funds in excess of a 3-month operating reserve necessary to fund operating costs at the beginning of the next fiscal year into the general fund.

Section 8. Section 17-7-502, MCA, is amended to read:

"17-7-502. Statutory appropriations -- definition -- requisites for validity. (1) A statutory

appropriation is an appropriation made by permanent law that authorizes spending by a state agency without the need for a biennial legislative appropriation or budget amendment.

(2) Except as provided in subsection (4), to be effective, a statutory appropriation must comply with both of the following provisions:

(a) The law containing the statutory authority must be listed in subsection (3).

(b) The law or portion of the law making a statutory appropriation must specifically state that a statutory appropriation is made as provided in this section.

(3) The following laws are the only laws containing statutory appropriations: 2-17-105; 5-11-120; 5-11-407; 5-13-403; 5-13-404; 7-4-2502; 7-4-2924; 7-32-236; 10-1-108; 10-1-1202; 10-1-1303; 10-2-603; 10-2-807; 10-3-203; 10-3-310; 10-3-312; 10-3-314; 10-3-316; 10-3-802; 10-3-1304; 10-4-304; 10-4-310; 15-1-121; 15-1-142; 15-1-143; 15-1-218; 15-1-2302; 15-31-165; 15-31-1004; 15-31-1005; 15-35-108; 15-36-332; 15-37-117; 15-39-110; 15-65-121; 15-70-128; 15-70-131; 15-70-132; 15-70-433; 16-11-119; 16-11-509; [section 7]; 17-3-106; 17-3-212; 17-3-222; 17-3-241; 17-6-101; 17-6-214; 17-7-133; 17-7-215; 18-11-112; 19-3-319; 19-3-320; 19-6-410; 19-9-702; 19-13-604; 19-17-301; 19-18-512; 19-19-305; 19-19-506; 19-20-604; 19-20-607; 19-21-203; 20-3-369; 20-7-1709; 20-8-107; 20-9-250; 20-9-534; 20-9-622; [20-15-328]; 20-26-617; 20-26-1503; 22-1-327; 22-3-116; 22-3-117; [22-3-1004]; 23-4-105; 23-5-306; 23-5-409; 23-5-612; 23-7-301; 23-7-402; 30-10-1004; 37-43-204; 37-50-209; 37-54-113; 39-71-503; 41-5-2011; 42-2-105; 44-4-1101; 44-4-1506; 44-12-213; 44-13-102; 50-1-115; 53-1-109; 53-6-148; 53-9-113; 53-24-108; 53-24-206; 60-5-530; 60-11-115; 61-3-321; 61-3-415; 67-1-309; 69-3-870; 69-4-527; 75-1-1101; 75-5-1108; 75-6-214; 75-11-313; 75-26-308; 76-13-150; 76-13-151; 76-13-417; 76-17-103; 77-1-108; 77-2-362; 80-2-222; 80-4-416; 80-11-518; 80-11-1006; 81-1-112; 81-1-113; 81-2-203; 81-7-106; 81-7-123; 81-10-103; 82-11-161; 85-20-1504; 85-20-1505; [85-25-102]; 87-1-603; 87-5-909; 90-1-115; 90-1-205; 90-1-504; 90-6-331; and 90-9-306.

(4) There is a statutory appropriation to pay the principal, interest, premiums, and any costs or fees associated with issuing, paying, securing, redeeming, or defeasing all bonds, notes, or other obligations, as due in the ordinary course or when earlier called for redemption or defeased, that have been authorized and issued pursuant to the laws of Montana. Agencies that have entered into agreements authorized by the laws of Montana to pay the state treasurer, for deposit in accordance with 17-2-101 through 17-2-107, as determined

1 by the state treasurer, an amount sufficient to pay the principal and interest as due on the bonds or notes have
2 statutory appropriation authority for the payments. (In subsection (3): pursuant to sec. 10, Ch. 360, L. 1999, the
3 inclusion of 19-20-604 terminates contingently when the amortization period for the teachers' retirement
4 system's unfunded liability is 10 years or less; pursuant to sec. 73, Ch. 44, L. 2007, the inclusion of 19-6-410
5 terminates contingently upon the death of the last recipient eligible under 19-6-709(2) for the supplemental
6 benefit provided by 19-6-709; pursuant to sec. 5, Ch. 383, L. 2015, the inclusion of 85-25-102 is effective on
7 occurrence of contingency; pursuant to sec. 6, Ch. 423, L. 2015, the inclusion of 22-3-116 and 22-3-117
8 terminates June 30, 2025; pursuant to sec. 4, Ch. 122, L. 2017, the inclusion of 10-3-1304 terminates
9 September 30, 2025; pursuant to sec. 1, Ch. 213, L. 2017, the inclusion of 90-6-331 terminates June 30, 2027;
10 pursuant to sec. 10, Ch. 374, L. 2017, the inclusion of 76-17-103 terminates June 30, 2027; pursuant to secs.
11 11, 12, and 14, Ch. 343, L. 2019, the inclusion of 15-35-108 terminates June 30, 2027; pursuant to sec. 1, Ch.
12 408, L. 2019, the inclusion of 17-7-215 terminates June 30, 2029; pursuant to secs. 1, 2, 3, Ch. 139, L. 2021,
13 the inclusion of 53-9-113 terminates June 30, 2027; pursuant to sec. 8, Ch. 200, L. 2021, the inclusion of 10-4-
14 310 terminates July 1, 2031; pursuant to secs. 3, 4, Ch. 404, L. 2021, the inclusion of 30-10-1004 terminates
15 June 30, 2027; pursuant to sec. 5, Ch. 548, L. 2021, the inclusion of 50-1-115 terminates June 30, 2025;
16 pursuant to secs. 5 and 12, Ch. 563, L. 2021, the inclusion of 22-3-1004 is effective July 1, 2027; pursuant to
17 sec. 1, Ch. 20, L. 2023, sec. 2, Ch. 20, L. 2023, and sec. 3, Ch. 20, L. 2023, the inclusion of 81-1-112, 81-1-
18 113, and 81-7-106 terminates June 30, 2029; pursuant to sec. 9, Ch. 44, L. 2023, the inclusion of 15-1-142
19 terminates December 31, 2025; pursuant to sec. 10, Ch. 47, L. 2023, the inclusion of 15-1-2302 terminates
20 June 30, 2025; pursuant to sec. 2, Ch. 374, L. 2023, the inclusion of 10-3-802 terminates June 30, 2031;
21 pursuant to sec. 12, Ch. 558, L. 2023, the inclusion of 20-9-250 terminates December 31, 2029; pursuant to
22 sec. 4, Ch. 621, L. 2023, the inclusion of 22-1-327 terminates July 1, 2029; pursuant to sec. 24, Ch. 722, L.
23 2023, the inclusion of 17-7-133 terminates June 30, 2027; pursuant to sec. 10, Ch. 758, L. 2023, the inclusion
24 of 44-4-1506 terminates June 30, 2027; and pursuant to sec. 10, Ch. 764, L. 2023, the inclusion of 15-1-143
25 terminates December 31, 2025.)"

26
27 **NEW SECTION. Section 9. Codification instruction.** [Sections 1 through 7] are intended to be
28 codified as a new chapter in Title 16, and the provisions of Title 16 apply to [sections 1 through 7].

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2 NEW SECTION. Section 10. **Effective date.** [This act] is effective January 1, 2026.

3 - END -