

1 _____ BILL NO. _____

2 INTRODUCED BY _____
3 (Primary Sponsor)

4 A BILL FOR AN ACT ENTITLED: "AN ACT CREATING THE KRATOM CONSUMER PROTECTION ACT;
5 PROVIDING DEFINITIONS; PROVIDING KRATOM PRODUCT LIMITATIONS; PROVIDING FOR KRATOM
6 PRODUCT REGISTRATION; PROVIDING FOR LABELING REQUIREMENTS; PROVIDING FOR
7 ENFORCEMENT BY THE DEPARTMENT OF REVENUE; PROVIDING FOR MISDEMEANOR AND FELONY
8 CONVICTIONS; PROVIDING RULEMAKING AUTHORITY; AND PROVIDING FOR CONTINGENT FEDERAL
9 PREEMPTION."

10

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

12

13 NEW SECTION. **Section 1. Short title.** [Sections 1 through 8] may be cited as the "Kratom
14 Consumer Protection Act".

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16 NEW SECTION. **Section 2. Definitions.** As used in [sections 1 through 8], the following definitions
17 apply:

18 (1) "Attractive to children" means kratom products manufactured in the shape of cartoons or
19 animals or manufactured or packaged in a form that bears any reasonable resemblance to an existing candy
20 product that is familiar to the public as a widely distributed, branded food product so that a kratom product could
21 be mistaken for the branded food product, especially by children.

22 (2) "Department" means the department of revenue provided for in 2-15-1301.

23 (3) "Distributor" means a person that sells, prepares, distributes, or maintains kratom products or
24 advertises, represents, or holds itself out as selling, preparing, or maintaining kratom products.

25 (4) "Independent testing laboratory" means a laboratory that is accredited by a third-party
26 accrediting body as a competent testing laboratory pursuant to the international organization for
27 standardization.

28 (5) "Kratom" means the plant *Mitragyna speciosa* or any part of that plant, including all

1 components present in the natural plant.

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

6 (7) "Kratom food service establishment" means any person who is a retailer that sells kratom as a
7 beverage prepared onsite or sells prepackaged kratom beverages or finished kratom products at a licensed
8 food service establishment.

9 (8) "Kratom product" means a food, food ingredient, dietary ingredient, dietary supplement, or
10 beverage intended for human consumption that contains any part of the leaf of the plant *Mitragyna speciosa* or
11 an extract of the *Mitragyna speciosa* leaf and is manufactured or served as a powder, capsule, pill, beverage,
12 liquid, or other edible form. A kratom product in any form that is combustible or intended to be used for
13 vaporization is prohibited.

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15 (9) "Registrant" means any person or entity responsible for placing a kratom product into
16 commerce in the state who must register under [section 4].

17 (10) "Retailer" means any person that sells, distributes, advertises, represents, or holds itself out as
18 selling kratom products.

19 (11) "Synthesized material" means an alkaloid or alkaloid derivative that has been created by
20 chemical synthesis or biosynthetic means, including but not limited to fermentation, recombinant techniques, or
21 yeast-derived enzymatic techniques rather than traditional food preparation techniques, such as heating or
22 extracting.

23

24 **NEW SECTION. Section 3. Kratom product limitations.** (1) A registrant may not prepare, distribute,
25 sell, or expose for sale a product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is
26 greater than 2% of the alkaloid composition of the kratom product. A product that contains a level of 7-
27 hydroxymitragynine greater than the 2% limit as provided in this subsection may not be marketed, labeled, or
28 contain any reference on its packaging that it is a kratom product or that it is derived from the alkaloid

1 mitragynine.

2 (2) (a) A registrant, distributor, or retailer may not offer for sale a kratom product that:

3 (i) contains a poisonous or otherwise deleterious non-kratom ingredient, including but not limited
4 to a substance listed as being controlled under state or federal law;

5 (ii) contains dangerous psychoactive compounds, including but not limited to synthetic
6 cannabinoids, synthetic cathinones, or any other compound that significantly alters the safety profile of the
7 kratom product;

8 (iii) is mixed with another compound that is known to inhibit key cytochrome P450 enzymes,
9 including CYP3A4 or CYP2D6. The kratom product must be considered to be adulterated unless the specific
10 product mixtures are scientifically validated as safe under the intended conditions of use and are specifically
11 permitted by the department.

12 (iv) is combustible, intended to be used for vaporization, or is injectable.

13 (b) Products that do not fall into the definition of a kratom product as provided in [section 2(8)] are
14 prohibited.

15 (3) A kratom product may not be manufactured in a manner that is attractive to children.

16 (4) A kratom product may not contain any synthesized material as provided in [section 2(10)] or
17 that contains alkaloids or other plant constituents that have been isolated or manipulated to artificially increase
18 their potency, other than using the approved extraction method provided in this section, unless the
19 manufacturer has safety data to support the increased potency according to the conditions for use on the label
20 in the populations the data supports.

21 (5) A kratom extract product may not contains levels of residual solvents higher than is allowed in
22 [section 2(6)].

23
24 NEW SECTION. **Section 4. Kratom product registration.** (1) The party responsible for placing a
25 kratom product into commerce in the state shall register annually to offer for sale kratom products
26 manufactured in an approved kratom delivery form and pay a fee, adjusted annually, to cover all administrative
27 costs for processing and administering the registrations, including the necessary staff and the publication and
28 maintenance of a kratom registration webpage as provided in subsection (5).

(2) Parties seeking to register a kratom product under subsection (3)(b) or (3)(c) must be required to pay a fee based on the costs the department incurs to retain the services of qualified experts to review the safety data provided by the registrant to allow the department to conduct a review and make a final decision.

(3) The registration must include the following sworn certifications from the processor:

(a) the kratom product was manufactured, processed, or held in a facility that is in compliance with current good manufacturing practices that meet the requirements of 21 CFR 111, as in effect on [the effective date of this act];

(b) a statement 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 any of the kratom products offered for sale.

(c) the submission of a certificate of analysis from a certified independent third-party laboratory showing compliance with the requirements of this chapter for residual solvents, 7-hydroxymitragynine content, contaminants, and synthesized materials.

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

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

NEW SECTION. Section 5. Labeling. A kratom product produced, manufactured, distributed, offered, sold, or offered for sale must have a label that clearly and conspicuously provides all of the following information on each retail package:

(1) a statement against the use by individuals who are under 18 years of age, who are pregnant, or who are breastfeeding;

(2) a recommendation to consult a health care professional prior to use;

(3) a statement that kratom may be habit-forming;

(4) the following statement: "These statements have not been evaluated by the United States Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

- 1 (5) the name and the address for the place of business of the registrant; and
- 2 (6) directions for use that include the following:
- 3 (a) a recommended amount of the kratom product for each serving that is:
- 4 (i) for product forms, such as capsules, gummies, prepackaged single serving units, and similar
- 5 product forms, clearly described on the label; or
- 6 (ii) for beverages, liquids, or loose powders, a clear instruction or a mark on the package or
- 7 container that clearly informs the consumer of the recommended serving size;
- 8 (b) a recommended number of servings that can be safely consumed in a 24-hour period;
- 9 (c) a listing of the servings for each container;
- 10 (d) a listing of kratom alkaloids and other ingredients in the product, including quantitative not-to-
- 11 exceed declarations of the amount for each serving of the following:
- 12 (i) Mitragynine; and
- 13 (ii) 7-hydroxymitragynine;
- 14 (e) a kratom food service establishment who sells kratom as a beverage prepared on-site shall
- 15 provide an equivalent label in card form or prominently display the required language in a location next to the
- 16 point-of-sale device to the customer at the time the beverage is purchased by the consumer; and
- 17 (f) a kratom product that contains psychoactive compounds otherwise permitted must be clearly
- 18 labeled with a full disclosure of all active ingredients, the exact concentration of each compound, and adequate
- 19 warning statements about the potential interactions and risks associated with the combined use of these
- 20 substances.
- 21

22 **NEW SECTION. Section 6. Enforcement -- criminal penalties.** (1) A registrant is prohibited from

23 selling a kratom product, a distributor is prohibited from distributing a kratom product, and a retailer is prohibited

24 from selling a kratom product that does not have a current registration with the department. The department

25 shall seize and destroy kratom products that are not registered. Costs associated with the department's actions

26 must be assessed to the party responsible for the kratom products' availability for sale in the state.

27 (2) Kratom products that are intended for human consumption may not be sold in this state to a

28 person who is under 18 years of age.

1 (a) A person who knowingly and willfully violates [sections 1 through 8] commits a misdemeanor
2 that is punishable as provided in Title 46.

3 (b) A person who knowingly and willfully commits a second or subsequent violation of [sections 1
4 through 8] within 1 year after the initial violation commits a second misdemeanor that is punishable as provided
5 in Title 46.

6 (3) A registrant that knowingly and willfully manufactures, delivers, holds, offers for sale,
7 distributes, or sells a kratom product that contains any controlled substance listed in state or federal law shall
8 be guilty of a felony as provided by state law.

9 (4) (a) A registrant that knowingly and willfully manufactures, delivers, holds, offers for sale,
10 distributes, or sells a kratom product that contains synthetic mitragynine, synthetic 7-hydroxymitragynine, or any
11 other synthetically derived compound of the plant *Mitragyna speciosa* commits a misdemeanor that is
12 punishable as provided by state law.

13 (b) Any violation of subsection (4)(a) must result in the immediate seizure and destruction of the
14 adulterated kratom products and may result in civil or criminal penalties. Repeat offenders are subject to
15 enhanced penalties, including permanent revocation of licenses to sell or distribute kratom products.

16 (5) (a) On receipt of a violation report on a kratom product offered for sale, the department shall
17 require the registrant to produce an updated and current certificate of analysis in a reasonable timeframe from a
18 certified independent third-party laboratory showing compliance with the requirements of this chapter for safe
19 kratom products.

20 (b) If the registrant does not provide the certificate of analysis in the specified timeframe, the
21 registration for the kratom product must be revoked and a stop sale order must be issued for kratom products
22 covered by this registration.

23 (6) (a) If the department has a reasonable basis to require an independent third-party test of a
24 registered kratom product by a laboratory of the department's choice, the registrant must be required to submit
25 payment for the test within a reasonable timeframe.

26 (b) If the registrant does not tender payment to the department within 30 days of receipt of the
27 invoice for the testing, the department shall revoke the registration for the kratom product and a stop sale order
28 must be issued for kratom products covered by this registration.

(7) A processor does not violate this section for any kratom product that has been reviewed and approved by the department for safe consumption in combination with psychoactive compounds under clearly defined conditions of use.

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

NEW SECTION. Section 7. Rules. The department shall adopt rules to administer the provisions of [sections 1 through 8]. The rules must provide for:

(1) the process for the registration of a kratom product by a processor, distributor, or retailer;

(2) the requirements for enforcing the restriction on the sale of any kratom product to a person under 18 years of age; and

(3) proof of appropriate quality testing from an ISO 17025 laboratory in the form of a certificate of analysis representing that the product does not contain levels of residual solvents, biological contaminants, or heavy metal contaminants that meets the standard for dietary supplement products.

NEW SECTION. Section 8. Federal preemption. If at any time on or after [the effective date of this act], the federal government or any department or agency of the federal government, including but not limited to the federal drug enforcement agency or the food and drug administration, regulates kratom, kratom extracts, kratom products, any other derivative of the plant *Mitragyna speciosa*, kratom processors, or kratom retailers, including the acceptance by the food and drug administration of a new dietary ingredient notification, those federal regulations must supersede and take precedence over any provision of [sections 1 through 8] and any administrative regulation promulgated under [sections 1 through 8] to the contrary that is addressed by the federal action.

NEW SECTION. Section 9. Codification instruction. [Sections 1 through 8] are intended to be codified as new chapter in Title 16 and the provisions of Title 16 apply to [sections 1 through 8].

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