SUBSTITUTE FOR HOUSE BILL NO. 5477

A bill to regulate the distribution, sale, and manufacturing of kratom products; to require licensing for certain conduct related to kratom and kratom products; to prohibit the distribution, sale, and manufacturing of certain kratom products; to provide for the powers and duties of certain state governmental officers and entities; to prescribe fines and sanctions; to provide remedies; and to require the promulgation of rules.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

- Sec. 1. This act may be cited as the "kratom consumer
 protection and regulatory act".
- 3 Sec. 3. As used in this act:
- 4 (a) "Certificate of licensure" means a document issued as5 evidence of authorization to distribute, sell, or manufacture a

- 1 kratom product.
- 2 (b) "Department" means the department of licensing and
- 3 regulatory affairs.
- 4 (c) "Director" means the director of the department or his or
- 5 her designee.
- 6 (d) "Food" means that term as defined in section 1107 of the
- 7 food law, 2000 PA 92, MCL 289.1107.
- 8 (e) "Kratom product" means a food that contains any part of
- 9 the leaf of the plant Mitragyna speciosa.
- 10 (f) "License" means an authorization granted by the department
- 11 under this act to distribute, sell, or manufacture a kratom
- 12 product.
- 13 (g) "Licensee" means a person that holds a license.
- 14 (h) "Rule" means a rule promulgated under the administrative
- 15 procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.
- Sec. 5. (1) Beginning January 1, 2023, a person shall not do
- 17 any of the following unless the person holds a license:
- 18 (a) Distribute a kratom product in this state.
- 19 (b) Sell a kratom product in this state.
- (c) Manufacture a kratom product in this state.
- 21 (2) A person shall obtain a license for each location in which
- 22 the person distributes, sells, or manufacturers a kratom product in
- 23 this state. A person shall obtain a license if the person
- 24 distributes, sells, or offers to distribute or sell a kratom
- 25 product through an online website to a person in this state.
- 26 (3) A person applying for a license under this section shall
- 27 do so on a form and in a manner prescribed by the department. An
- 28 application must include all of the following information:
- 29 (a) The applicant's full name, date of birth, telephone

- 1 number, and address. If the applicant is not an individual, the
- 2 application must include the EIN number of the applicant.
- 3 (b) The address of each business or location where a kratom
- 4 product will be distributed, sold, or manufactured or offered for
- 5 distribution or sale.
- 6 (c) A list of the kratom products that will be distributed,
- 7 sold, or manufactured or offered for distribution or sale at each
- 8 business or location described under subdivision (b).
- 9 (d) A copy of the certificate of analysis received under
- **10** section 13.
- 11 (e) A statement that the information supplied by the applicant
- 12 is, to the best of the applicant's knowledge, true and is signed
- 13 under penalty of perjury.
- 14 (4) The department shall grant an applicant a license under
- 15 this section if the applicant does all of the following:
- 16 (a) Submits a completed application under subsection (3).
- 17 (b) Submits an application fee of \$200.00.
- 18 (c) Meets the qualifications for a license specified under
- 19 this act.
- 20 (5) The department shall approve or deny an application for a
- 21 license not later than 30 business days after a completed
- 22 application is received. The department shall deny an application
- 23 for a license if the application is incomplete.
- 24 (6) If the department denies an application for a license
- 25 because it is incomplete, the department shall notify the applicant
- 26 in writing of the denial not later than 30 business days after the
- 27 application is received, state the deficiency, and request
- 28 additional information.
- 29 (7) A license is not transferable and is valid for 3 years.

- 1 (8) To renew a license, an applicant must do both of the
 2 following:
- 3 (a) Submit a completed application under subsection (3).
- 4 (b) Submit a renewal fee of \$125.00.
- 5 (9) A licensee shall prominently display the certificate of
- 6 licensure at each business or location where kratom products are
- 7 distributed, sold, or manufactured or offered for distribution or
- 8 sale.
- 9 Sec. 7. A kratom product must be labeled, and the product
- 10 label must contain the following information:
- 11 (a) Both of the following statements:
- 12 (i) "Mitragyna speciosa is an unapproved dietary ingredient.
- 13 Ingesting Mitragyna speciosa may be dangerous. Consult your
- 14 physician about whether this product is for you, how to use this
- 15 product safely, potential interactions, precautionary measures
- 16 before considering this product, and potential dependency,
- 17 seizures, and other possible complications. Inform your physician
- 18 of the alkaloid content labeled on this package.".
- 19 (ii) "Keep out of reach of children. DO NOT USE IF YOU ARE
- 20 PREGNANT, PLAN TO BECOME PREGNANT, OR WHILE BREASTFEEDING. NOT FOR
- 21 SALE TO MINORS.".
- (b) The alkaloid content in the kratom product.
- 23 (c) The amount of mitragynine and 7-hydroxymitragynine
- 24 contained in the kratom product.
- Sec. 9. A person shall not in person or through an online
- 26 website distribute, sell, manufacture or offer for distribution or
- 27 sale any of the following:
- 28 (a) A kratom product that is adulterated with a dangerous
- 29 nonkratom substance. A kratom product is adulterated with a

- 1 dangerous nonkratom substance if the kratom product is mixed or
- 2 packed with a nonkratom substance and that substance affects the
- 3 quality or strength of the kratom product to such a degree as to
- 4 render the kratom product injurious to a consumer.
- 5 (b) A kratom product that is contaminated with a dangerous
- 6 nonkratom substance. A kratom product is contaminated with a
- 7 dangerous nonkratom substance if the kratom product contains a
- 8 poisonous or otherwise deleterious nonkratom ingredient, including,
- 9 but not limited to, any of the substances listed in section 7212 of
- 10 the public health code, 1978 PA 368, MCL 333.7212.
- 11 (c) A kratom product that contains a level of 7-
- 12 hydroxymitragynine in the alkaloid fraction that is greater than 2%
- 13 of the alkaloid composition of the product.
- 14 (d) A kratom product that contains a synthetic alkaloid,
- 15 including, but not limited to, any of the following:
- 16 (i) Synthetic mitragynine.
- 17 (ii) Synthetic 7-hydroxymitragynine.
- 18 (iii) Any other synthetically derived compound of the plant
- 19 Mitragyna speciosa.
- (e) A kratom product that does not include on its package or
- 21 label the amount of mitragynine and 7-hydroxymitragynine contained
- 22 in the kratom product.
- 23 Sec. 11. (1) A licensee shall not in person or through an
- 24 online website distribute, sell, or offer for distribution or sale
- 25 a kratom product to an individual in this state who is under 21
- 26 years of age.
- 27 (2) A person shall not purchase a kratom product over the
- 28 internet in this state if the kratom product does not comply with
- **29** section 9.

- Sec. 13. (1) Before applying for a license under section 5, a person that wishes to distribute, sell, or manufacture or offer for distribution or sale a kratom product shall have a sample of the raw materials used to produce each kratom product tested by a qualified laboratory to certify that the kratom product does not contain any substance in violation of section 9.
 - (2) If raw materials tested under subsection (1) do not contain a substance in violation of section 9, the qualified laboratory shall provide the person with a certificate of analysis that states that the raw materials meet the requirements prescribed under this act.
 - (3) A person shall provide a copy of the certificate of analysis described under subsection (2) to the department with an application for a license under section 5 and upon request. The department may request that a person have a sample of raw materials retested by a qualified laboratory under subsection (1) and provide an updated certificate of analysis. If the department requests that a person have a sample of raw materials retested under this subsection, the person is responsible for the costs of the testing.
 - (4) As used in this section, "qualified laboratory" means a laboratory approved by the department by rule.
- Sec. 15. (1) After notice and an opportunity for a hearing under the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, a licensee may be subject to the following:
- 25 (a) For a violation of section 7, 9, or 11, an administrative 26 fine of not more than \$500.00 for the first offense and not more 27 than \$1,000.00 for a second or subsequent offense.
- (b) In addition to an administrative fine under subsection (a)or for any other violation of this act or a rule promulgated under

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- 1 this act, a denial, limitation, suspension, or revocation of a
- 2 license.
- 3 (2) A person that violates section 5(1) may be ordered to pay
- 4 a civil fine of not more than \$500.00 for the first offense and not
- 5 more than \$1,000.00 for a second or subsequent offense.
- **6** (3) In addition to any other action authorized by this act,
- 7 the director may bring an action to do 1 or more of the following:
- 8 (a) Obtain a declaratory judgment that a method, act, or
- 9 practice is in violation of this act.
- 10 (b) Obtain an injunction against a person that is engaging, or
- 11 about to engage, in a method, act, or practice that violates this
- **12** act.
- Sec. 17. By January 1, 2023, the department shall promulgate
- 14 rules pursuant to the administrative procedures act of 1969, 1969
- 15 PA 306, MCL 24.201 to 24.328, to implement this act.