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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2024

A N A C T

RELATING TO FOOD AND DRUGS -- KRATOM CONSUMER PROTECTION ACT

Introduced By: Representatives Edwards, Kennedy, and Solomon

Date Introduced: January 19, 2024

Referred To: House Corporations

It is enacted by the General Assembly as follows:

SECTION 1. Title 21 of the General Laws entitled "FOOD AND DRUGS" is hereby amended by adding thereto the following chapter:

CHAPTER 28.12

KRATOM CONSUMER PROTECTION ACT

21-28.12-1. Short title.

This chapter shall be known and may be cited as the "Kratom Consumer Protection Act."

21-28.12-2. Definitions.

As used in this chapter:

(1) "Civil division" means the unit under the civil division of the Rhode Island attorney general's office.

(2) "Food" means a dietary ingredient, dietary supplement, botanical supplement, or beverage for human consumption.

(3) "Kratom extract" means a dietary ingredient, dietary supplement, or botanical supplement containing any part of the leaf of the plant Mitragyna speciosa that has been extracted and concentrated in order to provide more standardized dosing.

(4) "Kratom product" means a dietary ingredient, dietary supplement, or botanical supplement, containing any part of the leaf of the plant Mitragyna speciosa or an extract of it; is manufactured as a powder, capsule, pill, beverage, or other edible form; and all kratom products are dietary ingredients, dietary supplements, or botanical supplements.

(5) "Processor" means a person that sells, prepares, manufactures, distributes, or maintains kratom products.

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

(7) "Court" means the superior court.

(8) "Underage individual" or "underage individuals" means any individual under the age of twenty-one (21) years.

21-28.12-3. Kratom product limitations.

A processor shall not prepare, distribute, sell, or advertise any of the following:

(1) A kratom product that is labeled as a food and deemed adulterated. A kratom product that is labeled as a food shall be deemed adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. If the substance is not an added substance such food shall not be considered adulterated if the quantity of the substance in such food does not ordinarily render it injurious to health.

(2) A kratom product that is labeled as a dietary supplement and deemed adulterated. A kratom product that is labeled as a dietary supplement shall be deemed adulterated if it contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.

(3) A kratom product that is contaminated with a dangerous non-kratom substance. A kratom product is contaminated with a dangerous non-kratom substance if the kratom product contains a poisonous or otherwise deleterious non-kratom ingredient including, but not limited to, the substances listed in § 21-28-2.08.

(4) A kratom extract that contains levels of residual solvents higher than is allowed in the U.S. Pharmacopeia 467.

(5) A kratom product containing any synthetic alkaloids including synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compounds of the kratom plant.

(6) A kratom product in any form that is combustible or intended to be used for vaporization.

(7) A kratom product in any form that mimics a candy product or is manufactured, packaged, or advertised in a way that appeals to underage individuals.

(8) A kratom product that does not provide adequate labeling directions necessary for safe and effective use by consumers, including:

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

(ii) A statement that kratom may be habit forming;

(iii) A recommendation against the use by individuals who are pregnant or who are breastfeeding;

(iv) 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.";

(v) The name and place of business of the processor, manufacturer, packer or distributor;

(vi) The net quantity of contents declared in numerical count (e.g., 30 capsules), or in volume or weight in United States Customary System terms;

(vii) Directions for use that include all of the following:

(A) A recommended amount of the kratom product per serving; and

(B) A recommended number of servings that can be safely consumed in a twenty-four (24) hour period.

21-28.12-4. Product Registration.

(a) A processor shall annually register each kratom product it manufactures, packs, distributes or labels with the civil division. A product that contains the same kratom ingredients in the same kratom delivery form, but a different container, package or volume, shall be included in a single registration.

(b) Annual registration of a kratom product shall include a certificate of analysis from an independent laboratory. The laboratory shall be accredited under the standards of the International Organization for Standardization 17025:2017 accreditation from an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement.

(c) The certificate of analysis shall include information on each of the kratom product components as described in this chapter.

(d) The processor registering each kratom product shall submit a sworn declaration to the civil division that the kratom product meets the requirements for registration and that no dangerous substances have been added to the kratom product being registered.

(e) The civil division may require an independent third-party test of a registered kratom product by a laboratory of the civil division's choice, and the processor shall be required to submit payment for the test. If the processor does not tender payment to the civil division within thirty (30) days of receipt of the invoice, the civil division unit shall revoke the registration for that product.

(f) Failure to submit a certificate of analysis shall be cause for denial of product registration.

(g) A retailer shall pay an annual registration fee set by the civil division prior to selling,

distributing or advertising kratom products.

(h) The civil division is authorized to establish an annual fee for a processor and a retailer to cover the administrative costs for processing and administering registrations.

21-28.12-5. Age limits.

A processor shall not distribute, sell, or advertise a kratom product to any underage individual.

21-28.12-6. Violations.

(1) A processor or retailer that negligently violates the provisions of this chapter shall be subject to a fine of not more than five hundred dollars ($500) for the first offense and not more than one thousand dollars ($1,000) for a second or subsequent offense. Upon the request of a person to whom a fine is issued, the civil division shall conduct a hearing in accordance with the procedures as set forth in chapter 35 of title 42 ("administrative procedures").

(2) Upon a third violation, the registration of the retailer shall be revoked, and the retailer shall be prohibited from selling any kratom product.

(3) A retailer is not in violation of the provisions of this chapter if it is shown 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.

(4) A person who intentionally, willfully or wantonly violates the provisions of this chapter shall be punished by a fine of up to one thousand dollars ($1,000) for the first offense, up to two thousand dollars ($2,000) for a second offense, and up to five thousand dollars ($5,000) for a third or subsequent offense.

(5) A person who intentionally, willfully or wantonly violates the provisions of this chapter by adulterating a kratom product with any substance listed in § 21-28-2.08 shall be subject to penalties set forth in this chapter as well as in § 21-28-4.01.

21-28.12-7. Taxation of kratom products.

A "kratom product" is subject to sales and use tax, at the rates provided in §§ 44-18-18 and 44-18-20.

21-28.12-8. Removal of mitragynine and 7-hydroxymitragynine from notice of designation of controlled substances under schedule I.

Upon enactment, mitragynine and 7-hydroxymitragynine shall be removed from § 21-28-2.08(g) of the Rhode Island uniform controlled substances act.

SECTION 2. Section 21-28-2.03 of the General Laws in Chapter 21-28 entitled "Uniform Controlled Substances Act" is hereby amended to read as follows:

21-28-2.03. Schedule I tests.

(a) The director of health shall place a substance in schedule I if he or she finds that the substance:

(1) Has high potential for abuse; and

(2) Has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

(b) Notwithstanding the provisions of subsection (a) of this section, the director shall have no authority to place or maintain mitragynine and 7-hydroxymitragynine in schedule I.

(c) Federal regulations. If the federal government or any department or agency thereof including, but not limited to, the federal Drug Enforcement Agency or Food and Drug Administration, issues any rules or regulations with respect to kratom, kratom extracts, kratom products, any other derivative of the plant mitragyna speciosa, kratom processors, or kratom retailers, such federal rules or regulations shall preempt any provision of this chapter.

SECTION 3. This act shall take effect on January 1, 2025.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO FOOD AND DRUGS -- KRATOM CONSUMER PROTECTION ACT

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This act would authorize and regulate the distribution of the product known as "kratom," and would ban the adulteration of kratom with a dangerous non-kratom substance as to render the product injurious to a consumer. The act would require that any kratom product contain adequate labeling directions necessary for safe and effective use by consumers.

This act would take effect on January 1, 2025.

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