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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. 2023

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A N A C T

RELATING TO FOOD AND DRUGS -- KRATOM CONSUMER PROTECTION ACT

Introduced By: Senators DiPalma, Miller, Euer, Acosta, and Gallo

Date Introduced: February 16, 2023

Referred To: Senate Judiciary

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) “Department” means the department of health.

(2) "Director" means the director of the department of health.

(3) "Food" means a food, food product, food ingredient, dietary ingredient, dietary supplement, or beverage for human consumption.

(4) “Kratom extract” means a food product or dietary ingredient containing any part of the leaf of the plant Mitragyna speciosa that has been extracted and concentrated in order to provide more standardized dosing.

(5) "Kratom product" means a food product or dietary ingredient containing any part of the leaf of the plant Mitragyna speciosa or an extract of it, and is manufactured as a powder, capsule, pill, beverage, or other edible form. All kratom products are foods.

(6) "Processor" means a person that sells, prepares, manufactures, distributes, or maintains

kratom products, or advertises, represents, or holds itself out as selling, preparing, or maintaining kratom products.

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

21-28.12-3. Kratom product limitations.

A processor shall not prepare, distribute, sell, or expose for sale any of the following:

(1) A kratom product that is adulterated with a dangerous non-kratom substance. A kratom product is adulterated with a dangerous non-kratom substance if the kratom product is mixed or packed with a non-kratom substance and that substance affects the quality or strength of the kratom product to such a degree as to render the kratom product injurious to a consumer.

(2) 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.

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

(4) A kratom product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than two percent (2%) of the overall alkaloid composition of the product.

(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 that does not provide adequate labeling directions necessary for safe and effective use by consumers, including a recommended serving size.

21-28.12-4. Age limits.

A processor shall not distribute, sell, or expose for sale a kratom product to an individual under eighteen (18) years of age.

21-28.12-5. Kratom product registration.

(a) A processor shall register annually any kratom product intended to be offered for sale to an end consumer in Rhode Island that is in an approved kratom delivery form and pay a fee, adjusted annually, to cover all administrative costs for processing and administering such registrations. The registration shall include a certificate of analysis from a certified independent third-party laboratory showing compliance with the requirements of this chapter for safe kratom products.

(b) Product non-compliance reports. Upon receipt of a violation report on any kratom product offered for sale, the department shall require the processor to produce an updated and

current certificate of analysis in a reasonable time frame from a certified independent third-party laboratory showing compliance with the requirements of this chapter for safe kratom products. If the processor does not provide the certificate of analysis in the specified time frame, the registration for that product shall be revoked.

(c) Adverse event reports. Upon receipt of any adverse event related to a registered kratom product, the processor shall be required to submit a copy via certified mail to the department their adverse event report that is required to be submitted to the U.S. Food and Drug Administration (FDA) under Section 761 of the Federal Food Drug & Cosmetic Act (21 U.S.C. §379aa-1(b)(1)). Any documented failure to report an adverse event to the department shall authorize the department to revoke the product's registration.

(d) Third-party verification: 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 processor shall be required to submit payment for the test within a reasonable time frame. If the processor does not tender payment to the department within thirty (30) days of receipt of the invoice for the testing, the department shall revoke the registration for that product.

21-28.12-6. Violations.

(a) A processor that violates the provisions of § 21-28.12-3 shall be subject to an administrative 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 an administrative fine is issued, the director shall conduct a hearing in accordance with the procedures as set forth in chapter 35 of title 42 ("administrative procedures").

(b) A retailer does not violate § 21-28.12-3 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.

SECTION 2. This act shall take effect on September 1, 2023.

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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 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. This act would require that any kratom product shall contain adequate labeling directions necessary for safe and effective use by consumers. Violations of this chapter would be subject to administrative fines from five hundred dollars ($500) to one thousand dollars ($1,000).

This act would take effect on September 1, 2023.

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