Memo

To: Assemblyman Duy Nguyen

From: David Goldwater, Pinyon Public Affairs

Date: March 20, 2023

Subject: Conceptual Amendment to AB 322, Kratom Protection Act

Assemblyman:

Here are the major revisions:

- Prohibit the Board of Pharmacy from scheduling kratom unless the Federal Government does so. Maybe;
    - NRS 453.2186 Board prohibited from including certain substances on schedule; exceptions; required considerations.

1. Authority to control pursuant to NRS 453.146, 453.218, 453.2182 and 453.2184 does not extend to distilled spirits, wine, malt beverages or tobacco.

(a) mitragynine or any of its constituent alkaloids can only be scheduled if designated as a controlled substance by federal law as provided in NRS 453.2182.

KRATOM CONSUMER PROTECTION ACT

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

Definitions.

As used in this chapter:

1) "Director" means the director of the department of Agriculture [or insert other department assignment].
2) "Food" means a food, food product, food ingredient, dietary ingredient, dietary supplement, or beverage for human consumption.
3) "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; is manufactured as a powder, capsule, pill, beverage, extract, or other edible form; and all kratom products are foods.
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 in order to provide more standardized dosing.

5) "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.
6) “Retailer” means any person that sells, distributes, advertises, represents, or holds itself out as selling or maintaining kratom products.

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 the state’s controlled substances list.
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 and alkaloid fraction that is greater than one percent (1%) 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) That does not provide adequate labeling directions necessary for safe use by consumers, including a recommended serving size, the recommended number of servings per day, and the number of servings in the package that is sold.

Age Limits.

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

Kratom Product Registration.

1) Processor Registration. A processor shall register annually any kratom product intended to be offered for sale to an end consumer 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 (COA) from a certified independent third-party laboratory showing compliance with the requirements for kratom products in this Act.
2) Product non-compliance reports. Upon receipt of a credible violation report of non-compliance with provisions of this Act on a kratom product offered for sale, the Department shall require the processor to produce an updated and current COA in a reasonable time frame from a certified independent third-party laboratory showing compliance with the KCPA requirements for safe kratom products. If the processor does not provide the COA in the specified time frame, the registration for that product is revoked.
3) Adverse Event Reports. Upon receipt of any adverse event (AE) related to a registered kratom product, the processor shall be required to submit a copy via certified mail to the Department of their AE 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. Any documented failure to report an AE to the Department shall authorize the Department to revoke the product's registration.
4) 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 a set time period upon receipt of the invoice for the testing, the Department shall revoke the registration for that product.

Violations.

1) A processor that violates this Act is 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 the state's administrative procedures act.

2) A retailer does not violate this Act 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,