AKA GMP Labeling Requirements

(1) **A kratom product produced, manufactured, distributed, offered, sold, or offered for sale shall have a label that clearly and conspicuously provides all of the following information on each retail package:**

a. A recommendation against the use by individuals who are under 18 years of age, who are pregnant, or who are breastfeeding.

b. A recommendation to consult a health care professional prior to use.

c. A statement that kratom may be habit forming.

d. 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."

e. The name and address of business of the registrant: the processor, distributor, or retailer responsible for placing the kratom product for sale.

f. Directions for use that include the following:

i. A recommended amount of the kratom product per serving that is (1) clearly described on the label for product forms such as capsules, gummies, prepackaged single serving units, and similar product forms; or (2) for beverages, liquids, or loose powders, a clear instruction or a mark on the package or container that clearly informs the consumer on the recommended serving size.

ii. A recommended number of servings that can be safely consumed in a 24-hour period.

iii. A listing of the servings per container.

iv. A listing of kratom alkaloids and other ingredients in the product, including quantitative not to exceed declarations of the amount per serving of each of the following:

1. Mitragynine.

2. A declaration that any level of 7-hydroxymitragynine does not exceed the alkaloid fraction that is greater than two percent (2%) of the overall alkaloid composition of the product.

a. Any product that contains a level of 7-hydroxymitragynine greater than this two percent (2%) limit cannot be marketed, labeled, or contain any reference on its packaging that it is a kratom product.

i. A kratom food service establishment who sells kratom as a beverage prepared on-site shall provide an equivalent label in card form or prominently display the required language in a location next to the point-of-sale device to the customer at the time the beverage is purchased by the consumer.

ii. Labeling and Disclosure Requirements

(1) Any kratom product that contains psychoactive compounds otherwise permitted must be clearly labeled with a full disclosure of all active ingredients, the exact concentration of each compound, and adequate warning statements about the potential interactions and risks associated with the combined use of these substances.