Basic Product Labeling
Guidelines

The Kratom Trade Association (KTA) is dedicated to the safe and responsible use of kratom botanical products in the U.S. KTA is committed to regulatory compliance and to developing and promoting use of best practices and quality standards for the industry. The following labeling guidelines reflect this commitment, in conformance with the U.S. Food and Drug Administration (FDA) labeling requirements. KTA is adopting FDA dietary supplement labeling "guidelines" for kratom as well as cGMP requirements.

Note: Supplement A contains state and local government specific legal requirements for labeling in those jurisdictions that are in addition to the guidelines below. Please check the supplement for locations where you sell product and incorporate as needed.

Q **Should I label my bulk or retail kratom product as "not intended for human consumption" or "botanical specimen"?**

A No. KTA is aware that some kratom manufacturers/processors/vendors add these dis-claimers to their products. KTA advises its members not to place such disclaimers on their labels.

Consistent with its commitment to safety and compliance, KTA urges its members to accurately characterize kratom products and avoid attempts to misrepresent the nature of the product. FDA and other governmental agencies are well aware that kratom is meant to be ingested and demonstrating this intention is typically not difficult. Intentionally mis-labeling the product not only is unlikely to protect your product from FDA regulatory action,[1] but also could lead to claims of false advertising and/or fraud, and could draw un-wanted comparisons to other products that have displayed such disclaimers, such as spice or bath salts.

Q **What content must appear on my label?**

A Six label statements are required:

Content	Description	Location on Label
1. Statement of identity	This is the common name of the supplement – it can either be simply "dietary supplement," or another appropriately descriptive term or ingredient can replace "dietary" (e.g., "herbal supplement," "botanical supplement"). Statement must stand out – use bold font and a font size reasonably related to the most prominent printed material on the PDP.	PDP[2] Must be placed in lines generally parallel to the base of the package

[1] For example, the highly publicized FDA-mandated Triangle recall involved a kratom product labeled as "bulk botanical sample".
[2] The Principal Display Panel ("PDP") is the label panel that faces the consumer when sitting on a shelf.

2. Net Quantity of Contents[3]	Amount of dietary supplement in the package/container. Must be expressed in weight or measure (metric and U.S. customary), or by numerical count (e.g., 100 tablets).	PDP Place in bottom 30% of PDP in lines generally parallel to the base of the package
3. Nutrition Labeling[4]	"Supplement Facts" panel – must list:[5] 1. Names and quantities of dietary ingredients present in the product (e.g., kratom) – NOTE: must include the part of the plant from which a dietary ingredient is derived (e.g., root, leaf) 2. Serving size 3. Number of servings in package (unless same as net quantity – e.g., if serving size is one gel cap and net quantity is 50 gel caps, it does not need to be repeated as number of servings) Some exemptions apply: • Small business – total annual gross sales to consumers of $500,000 or less or annual gross sales of food products (including dietary supplements) to consumers of $50,000 or less;[6] • Low volume business – sales of less than 100,000 units of product annually, fewer than 100 full-time equivalent employees and have filed an annual notification (stating that your business meets the exemption);[7] or • Bulk shipper – ships the product in bulk form, does not distribute to consumers in bulk form, and supplies for use in manufacture of other dietary supplements. • For retailers selling to consumers in bulk (e.g., barrel with a scoop), supplement facts must be provided on a sign or placard, or in booklet or binder at point of sale.	PDP or IP[8]

[3] For details, including required prominence and font size, see FDA Dietary Supplement Labeling Guide, Chapter III.
[4] For details, including required formatting, see FDA Dietary Supplement Labeling Guide, Chapter IV. If your product contains ingredients in addition to kratom, this chapter includes details on listing ingredients with established daily intake values, listing of liquid or dried extracts, proprietary blends, etc.
[5] If present in measurable amounts, must list total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron. (We assume this does not apply to most kratom products.)
[6] Labels, labeling, and advertising must not make a nutrient content or health claim.
[7] Labels, labeling, and advertising must not make a nutrient content or health claim.
[8] The Information Panel ("IP") is the panel located to the immediate right of the PDP as a consumer would view it. If the panel immediately to the right is unsuitable, the next panel immediately contiguous to the right may be used. If the PDP is the top of the package, any contiguous panel may be used.

4. Ingredient List[9]	If all source ingredients (e.g., kratom) are listed in the Supplement Facts panel, and there are no other ingredients, such as excipients or fillers, the ingredient list is not required. If other ingredients are included, list in descending order of prominence by weight. NOTE: If other ingredients in addition to kratom are included in your product, they must be generally recognized as safe (GRAS) or approved food additives. If you have any questions about other ingredients, please contact us.	PDP or IP Place immediately below Supplement Panel with no intervening material
5. Name and Place of Business	Can be the name/address of the manufacturer, packer or distributor. If not the manufacturer's information, must qualify the relationship (e.g., "distributed by," "packaged by") Can list either principal place of business or facility address (if different). Must list city/town, state and zip code. If not listed in the city directory or phone book, also must include street address.	PDP or IP
6. Country of Origin Labeling	Must list the country of manufacture, production, or growth of any imported article unless further work or material added in the U.S. effects a "substantial transformation." Customs rulings have consistently held that processing of bulk ingredients into tablets for retail sale do not substantially transform the product. Accordingly, if the kratom is of foreign origin, you are likely required to include a COO statement.	No specific placement required

Q What content am I permitted to place on my label in addition to required content?

A

Content	Description/Details
Brand name	Ensure that the brand name is not more prominent than the statement of identity
Recommended/ Suggested Use	Although this is not required, to encourage responsible use of the product, we recommend that you include this information. NOTE: Do not characterize this as "dosage" or "indications for use"

[9] For details, including required prominence and font size, see FDA Dietary Supplement Labeling Guide, Chapter V.

Symbols/Pictures	Ensure that any depiction does not imply a particular claim or otherwise misrepresent the contents of the product
Bar Code/UPC Code	(May be obtained from organizations like https://www.gs1us.org/)
Made in the U.S.A.	Likely inapplicable to kratom products – can only use this statement if reasonable basis to state that the product is in fact all or virtually all made in the United States. State law also may apply – e.g., in CA, merchandise or any article, unit, or part thereof, must be entirely or substantially made, manufactured, or produced in the U.S.
Expiration date	Should be supported by valid data demonstrating that it is not false or misleading
Company website/ social media information	CAUTION: Companies may include this information, but be aware that content of websites and social media ac-counts are considered by the FDA to be "labeling" for the product. Any content that you are not permitted to place on the label, especially certain claims, should not be available via a link placed on the product label.

Q Where on the label can I place voluntary content?

A There are no requirements for placement of voluntary content, but we note that FDA prohibits including any "intervening material" (i.e., non-required content) between label information that is required on the information panel. For example, you should not place a bar code between the supplement facts panel and the ingredient list.

Q What claims may I make about the product?

A CAUTION: At this time, due to the increased scrutiny on kratom products, we do not recommend making any claims about the product, as doing so may draw additional attention.

General Well-Being and Structure/Function Claims

To the extent you wish to make claims, you may make "general well-being" claims and/or "structure/function" claims.

- Structure/function claims generally describe the role of a dietary ingredient in-tended to affect the normal structure or function of the human body (e.g., "calcium builds strong bones") or characterize the role a dietary ingredient takes in main-taining such structure or function (e.g., "fiber maintains bowel regularity").
- General well-being claims describe general well-being from consumption of a di-etary ingredient. In order to make a "general well-being" or "structure/function" claim, you are re-quired to do the following:
  - Have substantiation that the claim is truthful and not misleading;
  - Include the following disclaimer on the product label: "This statement has not been evaluated by the Food and Drug Administration. This product is not intend-ed to diagnose, treat, cure, or prevent any disease;" and
  - Notify the FDA no later than 30 days after the first marketing of the product that you are making the relevant claim(s).

Nutrient Content Claims and Health Claims

The following claims typically are allowed for dietary supplements subject to certain conditions, but we do not expect that any kratom products would meet the necessary re-quirements to include such claims. We can provide additional information if needed:

- Nutrient content claims (including claims of "healthy," "high potency," "good source" or "antioxidant" – require presence of certain levels of specific nutrients depending on claim)
- Health claims (explicit or implied characterization of a relationship between a sub-stance and a health-related condition – must be authorized specifically by FDA)

"Organic" Claims or Descriptors
The U.S. Department of Agriculture regulates labeling and claims that describe ingre-dients and/or products as organic through its National Organic Program (NOP). To in-clude the word "organic" anywhere on the label, the ingredient or product must be certi-fied under the NOP. Accordingly, unless you or your supplier/manufacturer have NOP certification, refrain from using the word "organic" on the label.

"Natural" Claims
While FDA recently sought public comment on whether it should define "natural" claims, it has not initiated a rulemaking and there currently is no regulatory standard for making "natural" or "all natural" claims. The FDA has indicated that its longstanding policy has been to consider the "term 'natural' to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food." Accordingly, as long as calling your product "natural" is truthful and not misleading in accordance with FDA's policy, you may include "natural" on the label of your product.

Q What claims am I prohibited from making about the product?

A You must not make any claim – explicit or implied – that the product can be used to diagnose, cure, mitigate, treat, or prevent any disease. Such claims place the product in the unapproved new drug category. Even including the "Rx" symbol as part of your brand name, or including a picture of a stethoscope can be interpreted by the FDA to constitute a drug claim.

Q Must I include any warning statements on the label?

A We recommend including applicable dietary supplement warnings to encourage safe and responsible use of the product. These may include:

- Do not use this product if the safety seal on the bottle is broken.
- Do not use if you are under the age of 18 years or you are pregnant or lactating.
- Keep out of reach of children.
- Warning: Consult your health care professional prior to use if you have or suspect a medical condition, or are taking prescription drugs.
- Store in a cool, dry place.
- Do not drive or operate machinery.
- Do not consume alcohol when taking this product.

***These warnings are not meant to be all-inclusive. You should include any truthful warning that is necessary for the safe and responsible use of the product.

Q Do I need to worry about allergen labeling?

A You must not make any claim – explicit or implied – that the product can be used to diagnose, cure, Allergen labeling is only required if the following major allergens are included in your product: milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and/or soybeans.

We do not expect that kratom products will contain these allergens, and will not include details here. However, sometimes allergens, such as wheat or soy, appear in materials used to encapsulate drugs or dietary supplements, in anti-clumping agents, or in powders used to line certain packaging. If your product contains an allergen, please contact us for additional information.

Contact Information
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Supplement A: State and Local Labeling Requirements

Some state and local governments have enacted laws or regulations restricting sale to minors and/or requiring specific labeling statements for kratom products that must be applied in addition to FDA requirements. This Supplement A will be updated as new information is received. Each time a company begins selling in a new location, it should check this list to determine whether that location imposes additional requirements and ensure labels for those locations are compliant.

State and Local Labeling Requirements	
Denver, Colorado	The law requires that a consumer advisory shall be affixed to each package of kratom product in large font and easily readable to all purchasers, stating: "This product is not intended for human consumption. Consuming kratom products may pose a risk, including death, to consumers and has addictive potential. Increased risk of injury or death may be posed by consuming with alcohol and other drugs." Further, the label may not provide any guidance in regard to dosage or consumption of kratom. Reference: Denver Department of Environmental Health
Illinois	The sale to, purchase by and possession of kratom by individuals under the age of 18 is prohibited. KTA recommends the following statement be added to products labeled for sale in Illinois: "Sale to and possession of kratom by persons under the age of 18 is prohibited by law." Reference: Illinois Kratom Control Act NOTE: Sale of Kratom is completely prohibited in Alton, IL and Jerseyville, IL.
Minnesota	Effective August 1, 2018, the sale of kratom to individuals under the age of 18 is prohibited, and it is illegal for persons under age 18 to possess it. KTA recommends the following statement be added to products labeled for sale in Minnesota: "Sale to and possession of kratom by persons under the age of 18 is prohibited by law." Reference: Engrossed Senate Bill SF2578 (signed by the Governor on May 29, 2018)
Tennessee	Newly passed Tennessee legislation makes it illegal to sell kratom to persons under the age of 21 and unless it contains the following statement on its label: "Warning: Do not use if you are pregnant or nursing. It is illegal to possess Kratom if under 21 years of age. Consult your healthcare professional before using. Do not combine with alcohol or medication. Consult a doctor prior to usage if you have any heart disease, liver disorder, high blood pressure, or medical condition or take medication." Reference: Tennessee Code Annotated, Section 39-17-452(a)(3) (signed by Governor May 21, 2018) Note: The law also prohibits the sale of kratom products unless the kratom is in its "natural form," which the law defines as "dried, cut, and sifted Kratom leaf or raw Kratom leaf powder."

As a reminder, the sale of Kratom is completely banned in the following states and localities:			
• Alabama • Alton, IL • Arkansas	• Jerseyville, IL • Rhode Island • San Diego, CA	• Sarasota County, FL • Union City, MS • Vermont	• Washington, DC • Wisconsin