DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
College Park, MD 20740

Mr. Luke Dodd
11133 State Highway 176
Walnut Shade, Missouri 65771-9124

SEP 2 2 2015

Dear Mr. Dodd:

This letter is to inform you that the Food and Drug Administration filed your notification, dated August 10, 2015, which you submitted to the Food and Drug Administration (FDA) pursuant to 21 United States Code (U.S.C.) § 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) on August 18, 2015. Your notification concerns a dietary supplement containing a new dietary ingredient which is derived from an extract of "*Mitragyna speciosa* (aka Kratom)" that you plan to market under the trade name of "Atomic K".

Your notification contains the following conditions of use: Each capsule will contain 400 mg of extract. Take up to two times a day for a maximum daily serving level of 800 mg of extract. "This product will not be sold to any persons under the age of 18. A warning label stating; not to be taken if pregnant, nursing, and have current health issues. Each package only contains one doses [sic] at a time maximum limited to two doses per day."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Title 21 of the Code of Federal Regulations (CFR) §190.6 was written to inform notifiers how to comply with the federal statute (21 U.S.C. 350b(a)(2)) establishing the requirements for a new dietary ingredient notification. Your notification concerning the above-mentioned new dietary ingredient does not comply with the requirements of 21 CFR 190.6 and is incomplete for the following reasons:

- Under 21 CFR 190.6(b)(2), you are required to provide the name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial (including the author) of any herb or other botanical. Your notification provides the Latin binomial name of *Mitragyna speciosa*, but you did not provide the author. Our NDI draft guidance also provides the following advice: "You must

provide the Latin binomial name, including the author citation, for any ingredient that is a botanical or derived from a botanical.... We recommend that you also specify the part of the plant from which the ingredient is derived. You may, in addition, provide a common or usual name for your botanical ingredient. The Latin binomial name should be in accordance with internationally accepted rules on nomenclature, such as those found in the International Code of Botanical Nomenclature [Now known as International Code of Nomenclature for algae, fungi, and plants (ICN)][1]. FDA recommends using the most recent edition of ICN. We also recommend providing the following to help us evaluate whether your botanical ingredient is the same as or similar to botanical ingredients described in the history of use or other safety evidence in your notification:

- Description of specific tests or examinations you use to ensure correct taxonomic identity, including identification of any authenticated botanical reference materials or authoritative botanical descriptions used;
- Conditions of propagation, if they involve deliberate manipulation of propagation in a manner that is significantly different than common plant propagation and breeding practices;
- Conditions of cultivation (e.g., wild harvest, field, or greenhouse) and geographical origin of plant material, if necessary to accurately identify the NDI or relevant to your conclusion that the ingredient is reasonably expected to be safe."

Periods during which the botanical is cultivated and harvested (season or month(s) and year, age of plant, or both) and the stage of maturity of the harvested plant part;
The part of the plant from which the ingredient is derived;

- Whether the botanical is used in a fresh or dehydrated state;
- The form in which the botanical is used (e.g., whole, chopped, cut-and-sifted, or powdered);
- A properly prepared and curated voucher of the botanical source material; and
- The full Latin binomial name (with author) of any known adulterant species that must be excluded from use in production of the NDI, and a description of how its use is excluded."

- Under 21 CFR 190.6(b)(4), you are required to provide history of use or other evidence of safety to comply with the statutory requirement for a reasonable expectation of safety. You provided FDA with a minimal amount of history of use information and none of that information could be used as a basis to conclude that your dietary supplement containing such a new dietary ingredient would have a reasonable expectation of safety. Under your conditions of use, you propose a maximum daily serving level of 800 mg of extract, but you provide no safety data to ensure that this level (or any serving level of your product of commerce) has a reasonable expectation of safety. Neither did you demonstrate a qualitative and quantitative comparison of your product of commerce to the amount of extract or herb consumed historically.

In addition, under 21 U.S.C. § 321(g)(1)(B), the term "drug" means "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." The

[1] McNeill, J.; Barrie, F.R.; Buck, W.R. et al., editors. International Code of Nomenclature for algae, fungi, and plants (Melbourne Code) 2012 (electronic ed. http://www.iapt-taxon.org/nomen/main.php).

information contained in your notification suggests that "Atomic K" is a drug. For example, you state in your notification that "Atomic K" "...behaves as a mu-opioid receptor agonist like morphine and is used in the management of chronic pain." Since you have not shown that "Atomic K" has been marketed as a dietary ingredient; and the active moiety [the physiological or pharmacological action -- see 21 CFR 314.108(a)] of "Atomic K" functions as a drug; your product is intended for use as a drug within the meaning of 21 U.S.C. § 321(g)(1)(B), and is subject to regulation under the drug provisions of the Act. You should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, 10903 New Hampshire Avenue, W051-5185, Silver Spring, MD 20993-0002 if you want to investigate the possibility of marketing "Atomic K" as a drug.

Because your notification is incomplete as outlined above, FDA could not evaluate the identity and safety of your dietary supplement containing the new dietary ingredient.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the dietary supplement product you call "Atomic K" when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of August 18, 2015. After the 90-day date, the notification will be placed on public display at www.regulations.gov as new dietary ingredient notification report number 881. Prior to that date, you may wish to identify in writing specifically what information you believe is trade secret or confidential commercial information and an explanation of the basis for this belief.

If you have any questions concerning this matter please contact Dr. Fred Hines, Consumer Safety Officer (CSO), New Dietary Ingredients Review Team, at (240) 402-1756.

Sincerely,

Robert Durkin

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(Acting) Director
Division of Dietary Supplement Programs
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