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Kratom Exchange - Warning Letter - Letter Issued: 06/30/2022

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CMS 633972

Delivery Method:

Via Email

Product:

Drugs

Recipient:

Kratom Exchange

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United States

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Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

[Federal Trade Commission](#)

WARNING LETTER

June 30, 2022

RE: 633972

Dear Kratom Exchange:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at <https://www.kratomexchange.com/> in May 2022 and June 2022, respectively, and have determined that you take orders there for kratom products such as "Red Maeng Da Kratom Powder," "Super Green Kratom Powder," "White Maeng Da Kratom Powder," and other varieties listed under Red Vein Kratom, White Vein Kratom, Green Vein Kratom, and Yellow Kratom product categories. We have also reviewed your Twitter social media website at https://twitter.com/Kratom_Exchange, which directs consumers to your website <https://www.kratomexchange.com/> to purchase your products. The claims on your website and social media website establish that your products are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a) and 331(d). As explained further below, introducing or delivering these products for introduction into interstate commerce violates the FD&C Act.

The Department of Health and Human Services (HHS) has determined that a public health emergency exists nationwide involving the opioid crisis.¹ You market kratom products for the treatment or cure of opioid addiction and withdrawal symptoms. However, these products have not been determined by FDA to be safe and effective for these (or any other) uses. Further, the unproven treatments could cause patients to forego or delay FDA-approved treatments for opioid addiction or withdrawal. The marketing and sale of unapproved opioid addiction treatment products is a potentially significant threat to the public health. Therefore, FDA is taking measures to protect consumers from products that, without approval by FDA, claim to diagnose, mitigate, prevent, treat or cure opioid addiction.

Unapproved New Drugs

Your kratom products are drugs under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or intended to affect the structure or any function of the body.

Examples of claims observed on your website and social media website that establish the intended use of your products as drugs include, but may not be limited to, the following:

Red Maeng Da Kratom Powder

On the product webpage for "Red Maeng Da Kratom Powder,"<https://www.kratomexchange.com/product/red-maeng-da-kratom/>:

- "Red vein Maeng Da Kratom has a high alkaloid count . . . and helps ease opioid withdrawal symptoms . . . red strain can also help you reduce . . . depression."

Super Green Kratom Powder

On the product webpage for "Super Green Kratom Powder,"<https://www.kratomexchange.com/product/super-green-kratom/>:

- "Super Green Kratom . . . lowers blood pressure."

White Maeng Da Kratom Powder

On the product webpage for "White Maeng Da Kratom Powder,"<https://www.kratomexchange.com/product/white-maeng-da-kratom/>:

- "White Maeng Da Kratom . . . relieves opiate cravings, depression, and much more."

From a May 10, 2022 blog post entitled, "SIGNIFICANCE OF KRATOM FOR BEATING THE WINTERS,"<https://www.kratomexchange.com/significance-of-kratom-for-beating-the-winters/>:

- "KRATOM CAN HELP WITH OPIOID ADDICTION DURING WINTER . . . Kratom can treat opioid addiction without causing any adverse effects. It helps in overcoming the Morphine and ethanol withdrawal symptoms. It's a herbal technique to speed up the process of de-addiction therapy and overall health improvement."
- "Anxiolytic drugs such as kratom leaves can aid in the treatment of . . . depression"

From a December 7, 2021 blog post entitled, "WHAT ARE THE HEALTH BENEFITS OF KRATOM?,"<https://www.kratomexchange.com/what-are-the-health-benefits-of-kratom/>:

- "OPIOID ADDICTION[,] One of the main reasons I turned to kratom was because of my opioid abuse. This is why Kratom Exchange is so personal, I'm a living example of how it can change your life. Reports show that kratom is an effective treatment for opioid addiction. It has been proven to help alleviate the withdrawal symptoms of morphine and strong opioids."
- "MOOD ENHANCEMENTS[,] A wide range of users that suffer from depression have reported that it helps their anxiety and depression."

From a January 23, 2019 blog entitled, "RED KRATOM: WHAT YOU NEED TO KNOW,"<https://www.kratomexchange.com/red-kratom/>:

- "While Kratom effects differ from one person to the next, kratom users have stated it helps with . . . depression . . . PTSD"

From a September 3, 2018 blog entitled, "10 AMAZING KRATOM BENEFITS YOU NEED TO KNOW,"<https://www.kratomexchange.com/10-amazing-kratom-benefits-you-need-to-know/>:

- "HOW KRATOM BENEFITS YOUR HEALTH . . . BOOSTS IMMUNE FUNCTION . . . It's particularly

- effective against antibiotic-resistant bacteria, such as *Bacillus subtilis* and *Salmonella typhi*."
- "WARDS OFF DEPRESSION . . . White, Thai, and maeng da strains work best for depression treatment"
 - "SUPPORTS CARDIOVASCULAR HEALTH . . . It may also decrease blood pressure . . . Additionally, kratom regulates blood sugar levels, which further reduces the risk of diabetes and heart disease. This makes it popular among people with hypertension, insulin resistance, metabolic syndrome, and poor circulation."

From a July 27, 2016 blog entitled, "CAN KRATOM HELP WITH OPIATE WITHDRAWAL?",
"<https://www.kratomexchange.com/can-kratom-help-with-opiate-withdrawal/>:

- "Kratom may help with opiate withdrawal . . . HOW COULD KRATOM HELP WITHDRAWAL FROM OPIATES: Kratom mimics the effects of opioid drugs such as heroin, morphine, oxycodone, hydrocodone and so on. The major alkaloid in Kratom, Mitragynine, is a partial opioid agonist producing similar effects to morphine. Another interesting minor alkaloid of Kratom is 7-hydroxymitragynine that is reported to be more powerful than morphine. However, both Kratom alkaloids activate supraspinal mu- and delta-opioid receptors, are the major reasons that the plant reduces withdrawal symptoms as well."
- "BEST KRATOM FOR OPIATE WITHDRAWAL . . . While many prefer white strains for the energizing effects, the best Kratom for opiate withdrawal seems to be red strains . . . Thus, it is one of the most desirable for opiate withdrawal than other stimulating types of Kratom."

From your Twitter social media account, https://twitter.com/Kratom_Exchange:

- April 18, 2019 Retweet - "#Kratom users claim it helps them manage the symptoms of . . . #depression."

Your kratom products are not generally recognized as safe and effective for their above referenced uses and, therefore, these products are "new drugs" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 355(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective. There are no FDA-approved applications in effect for any of your kratom products.

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA and FTC laws and regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and injunction.

Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance, by email to FDAADVISORY@fda.hhs.gov.

FTC Cease and Desist Demand: In addition, it is unlawful under the FTC Act, 15 U.S.C. §§ 41-57, to advertise that a product can prevent, treat, or cure human disease, including addiction to alcohol, nicotine, or drugs, unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For addiction, no such study is currently known to exist for kratom. Thus, any addiction treatment claims regarding such products are not supported by competent and reliable scientific evidence. **You must immediately cease making all such claims** and staff strongly suggests that you review all health-related claims that you or any of your affiliates are making in any medium to ensure that they are properly substantiated and do not violate the FTC Act. **Violations of the FTC Act may result in legal action seeking a Federal District Court injunction. In addition, pursuant to Section 8023 of the Opioid Addiction Recovery Fraud Prevention Act of 2018,**

15 U.S.C. § 45d, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of any substance use disorder, including addiction to alcohol, nicotine, or drugs, are subject to a civil penalty of up to \$46,517 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b).

With regard to the advertising claims discussed above, within fifteen (15) working days of receipt of this letter, please notify Rick Quaresima, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rquaresima@ftc.gov of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Quaresima at (202) 326-3130.

Sincerely,

/S/

Donald D. Ashley

Director

Office of Compliance

Center for Drug Evaluation and Research

Food and Drug Administration

Sincerely,

/S/

Serena Viswanathan

Associate Director

Division of Advertising Practices

Federal Trade Commission

1 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued October 26, 2017, and subsequently renewed), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

Content current as of:

07/05/2022

Regulated Product(s)

- Drugs

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