


WARNING LETTER

Omni Consumer Products LLC d/b/a YoKratom

MARCS-CMS 634184 — JUNE 30, 2022

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Delivery Method:

Via Email

Product:

Drugs

Feedback


Recipient:

Omni Consumer Products LLC d/b/a YoKratom

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United States

 help@yokratom.com (mailto:help@yokratom.com)

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

 Federal Trade Commission

WARNING LETTER

June 30, 2022

RE: 634184

Dear Ben Harrison:

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://yokratom.com/> in May 2022 and June 2022, respectively, and have determined that you take orders there for all varieties of your “Red Maeng Da Kratom,” “Red Borneo Kratom,” “Red Bali Kratom,” “White Maeng Da Kratom,” and “White Borneo Kratom” powder and capsule products (herein referred to as “your kratom products”). The claims on your website establish that your kratom 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.⁷ You market your 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, <https://yokratom.com/>, that establish the intended use of your products as drugs include, but may not be limited to, the following:

On your webpage <https://yokratom.com/product-category/shop-by-kratom-strain/red-maeng-dakratom/>:

- **Red Maeng Da Kratom[:]** Red vein kratom is best known for its sedative and relaxing effects . . . For users looking for a great alternative to pharmaceutical pain pills, this variation is great for pain relief and pain management. Many users also find that Red vein is helpful [sic] opioid withdrawal symptoms and management.”

On your webpage <https://yokratom.com/product-category/shop-by-kratom-strain/red-borneokratom/>:

- **“Red Borneo Kratom** . . . this strain works best as a sedative and [sic] great for heroin and opiate withdrawal . . . If you are experiencing withdrawal from opiates or heroin then this is our top choice for you.”

On your webpage <https://yokratom.com/product-category/shop-by-kratom-strain/red-balikratom/>:

- **“Red Bali Kratom** . . . Bali is great for heroin and opiate withdrawal providing . . . sedative effects. If you are experiencing pain this is the strain for you, with most users reporting great pain management results with Bali.”

On your webpage <https://yokratom.com/product-category/shop-by-kratom-strain/white-maengda-kratom/>:

- **“White Maeng Da Kratom[:]** White Vein users report . . . mood enhancing effects . . . Some users use this variety to . . . prevent mood swings and help fight depression.”

On your webpage <https://yokratom.com/product-category/shop-by-kratom-strain/white-borneokratom/>:

- **“White Borneo Kratom** . . . this strain works best as a sedative and [sic] great for heroin and opiate withdrawal . . . If you are experiencing withdrawal from opiates or heroin then this is our top choice for you.”

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 the above-mentioned 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 (tel: (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> (<https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>).

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