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Herbsens Botanicals - Warning Letter - Letter Issued: 06/30/2022

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CMS 634373

Delivery Method:

Via Email

Product:

Drugs

Recipient:

Herbsens Botanicals

Plant City, FL 33563

United States

Info@herbsenskratom.com

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

[Federal Trade Commission](#)

WARNING LETTER

June 30, 2022

RE: 634373

Dear Herbsens Botanicals:

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://herbsenskratom.com/> in May 2022 and June 2022, respectively, and have determined that you take orders there for numerous kratom capsule and powder products, including but not limited to "Kratom Red Maeng da," "Kratom Green Malay," and "Kratom Train wreck" (hereinafter 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.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, <https://herbsenskratom.com/>, that establish the intended use of your kratom products as drugs include, but may not be limited to, the following:

On the blog post titled, "Best Kratom for Pain and Energy 2021"<https://herbsenskratom.com/blog/best-kratom-for-pain-and-energy-2021/>:

- "Maeng Da Kratom strain is well known for pain relief . . . Red vein Kratom not only reduces pain but's [sic] also your go-to mood lifter . . . The strain contains analgesic and opioid-like properties that may help concentration and focus on task."

On the blog post titled, "How long Kratom Capsules Takes to Kick In?"<https://herbsenskratom.com/blog/how-long-kratom-capsules-takes-to-kick-in/>:

- "Kratom is commonly used to manage several health challenges, including: • Withdrawal from Morphine, heroin, and related opioids . . . • Depression . . . • Diabetes . . . • High blood pressure"

On the blog post titled, "Kratom and Low Blood Pressure"<https://herbsenskratom.com/blog/kratom-and-low-blood-pressure/>:

- "Kratom has been used to manage numerous conditions, including opioids withdrawal symptoms."
- "[M]any Reddit users attest to Kratom's ability to improve blood pressure."

On the blog post titled, "Kratom Drug Interactions - Never Combine Them"<https://herbsenskratom.com/blog/kratom-drug-interactions-never-combine-them/>:

- "In the US, Kratom is basically used to: • Self-treat acute and chronic pain • Manage opioid addiction • Manage emotional or mental health conditions"

On the blog post titled, "Kratom Extract Vs. Powder - Know What Is Best for You?"<https://herbsenskratom.com/blog/kratom-extract-vs-powder-know-what-is-best-for-you/>:

- "Kratom may help handle a wide range of health concerns - from PTSD to addiction."
- "In large measures, the plant produces opioid-like sedative effects. For this, the plant is a common recommendation to manage opioid addiction."

On the blog post titled, "Kratom's Strain Chart"<https://herbsenskratom.com/blog/kratomsstrain-chart/>:

- "Some medical benefits of Kratom [:] • It improves your immunity and body's ability to fight dieses [sic] • Helps to control your blood sugar"
- "Overall Kratom is better and well tolerated compare [sic] to opiate painkiller."

On the blog post titled, "Which is The Best Kratom for Sleep? How To Use It?"<https://herbsenskratom.com/blog/which-is-the-best-kratom-for-sleep-how-to-use-it/>:

- "Although Kratom products are primarily known to manage sleeplessness symptoms, it's also purported great for pain, opioid cessation, anxiety, and depression. The substance delivers similar effects like the more-common morphine and codeine products."

On the blog post titled, "What are the Green Malay Kratom Effects?"<https://herbsenskratom.com/blog/what-are-the-green-malay-kratom-effects/>:

- "BENEFITS OF GREEN MALAY KRATOM [:] • Treats Osteoporosis . . . • Powerful Antidepressant"

On the blog post titled, "Kratom Vs Delta 8 CBD"<https://herbsenskratom.com/blog/kratomvs-delta-8-cbd/>:

- "In the US, the major reasons for Kratom use are to self-treat acute and chronic pain, manage opioid and/or heroin addiction, and to manage emotional or mental health concerns."

On the product webpage for "Kratom Train Wreck Capsules 300CT"<https://herbsenskratom.com/product/95-kratom-train-wreck-300ct/>:

- "Our kratom train wreck is a unique blend of 11 different strains of kratom. It's also the perfect way to get through a physical opioid withdrawal."

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.

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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