WARNING LETTER

Kratom Spot

MARCS-CMS 552370 — MAY 18, 2018

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Delivery Method:

Overnight Delivery

Recipient:

Kratom Spot
16755 Von Karman Avenue
Irvine, CA 92606
United States

Issuing Office:

Center for Drug Evaluation and Research
United States

U.S. FOOD & DRUG ADMINISTRATION

10903 New Hampshire Avenue
Silver Spring, MD 20993

May 18, 2018

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Kratom Spot
16755 Von Karman Avenue
Irvine, CA 92606

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.kratomspot.com

in April 2018 and has determined that you take orders there for various kratom products, including but not limited to, “Red Thai Kratom Powder,” “Green Thai Kratom Powder,” “Indo White Vein Kratom Powder,” “Bali White Vein Kratom Powder,” “White Vein Sumatra Kratom Powder,” “Indo Green Vein Kratom Powder,” “Borneo White Vein Kratom Powder,” “Red Vein Indo Kratom Powder,” “Green Malay Kratom Powder,” “Sumatra Red Vein Kratom Powder,” “Bali Red Vein Kratom Powder,” “Red Thai Kratom Capsules,” “Ultimate White Vein Borneo Kratom Capsules,” “Maeng Da Kratom Powder,” “Green Malay Kratom Capsules,” “White Maeng Da Kratom Powder,” “Red Maeng Da Kratom Powder,” “Super Green Indo Kratom Capsules,” “Sumatra Red Vein Kratom Capsules,” “Red Vein Malay Kratom Capsules,” “Indo White Vein Kratom Capsules,” “Maeng Da Kratom Capsules,” “Ultra Enhanced Malay Kratom Powder,” “Ultra Enhanced Bali Kratom Powder,” “Ultra Enhanced Borneo Kratom Powder,” “Ultra Enhanced Indo Kratom Powder,” “Ultra Enhanced Sumatra Kratom Powder,” “Kratom Extract 8x Kratom Powder,” and “Ultra Enhanced Maeng Da Kratom Powder.” We have also reviewed your social media websites at www.facebook.com/kratomspotonline.com and www.twitter.com/kratomspot. FDA has determined that these products are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 355(a) and 331(d). Furthermore, these products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. 352. You can find the FD&C Act and FDA regulations through links on FDA’s home page at www.fda.gov (/home).

On October 26, 2017, the Acting Secretary of the Department of Health and Human Services, under section 319 of the Public Health Service Act, 42 U.S.C. 274d, determined that a public health emergency exists nationwide involving the opioid crisis. As described in more detail below, you market various kratom products for, among other things, 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 and 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 and Misbranded Drugs

The claims on your website and social media sites establish that the above-mentioned products are drugs as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the FD&C Act.

Examples of labeling claims observed on your website, www.kratomspot.com, that establish the intended use of your products include, but may not be limited to, the following:

On the page of your website titled “Blog: The Opioid Epidemic and the Kratom Possible Solution: How Can Kratom help The Opioid Crisis?”:

- “[Kratom] has natural pain relief properties and has been shown to be safe for use. Kratom offers people who suffer from chronic pain an option to synthetic drugs altogether.”
- “Many of our customers have reported that kratom has helped them quit the use of heroin and synthetic drugs. The mood elevation qualities of kratom reduces opiate withdrawal effects.”
- “A quick look at our product reviews reveals hundreds of testimonials on how this amazing herb helped people kick addiction and thwart pain.”

On the page of your website titled “Blog: How to Quit Opiate Drugs with Kratom?”:

- “Are you one of those who is keen on stopping opiate drugs? Well, we have an excellent solution for your problem. The answer is herbal solution – Kratom plant, also known as Mitragyna speciosa.”
- “The best kratom to quit opiate drugs is Classic Red Bali, also known as Red Indo Kratom. It is a powerful sedative and painkiller. Therefore, it is all the more advantageous in fighting against opiate addiction.”
- “The Red Vein type of Kratom is more desirable to use to quit opiates because it can relieve the withdrawal symptoms well. It is a healthy and natural way to overcome opiate drug addiction. Whether you are a victim of heroin addiction or addicted to oxycodone, hydrocodone, suboxone, or methadone, Kratom can successfully eliminate opiate withdrawal symptoms for you.”
- “Mitragynine has considerable effect in controlling opiate addiction.”

- “How I overcame Methadone addiction with Kratom? . . . If you wish to break free from the clutches **opiate addiction**, you should try out Kratom . . . Buy Kratom right away and pave your way to deaddiction through this South East Asian wonder plant.”

On the page of your website titled “Blog: Which types of Kratom are used for opiate withdrawal?”:

- “It has been known for quite some while now that Kratom is useful in the withdrawal from opiate addiction.”
- “It helps in reduction of insomnia and pain associated with withdrawal. Also, it uplifts mood and acts like an anxiolytic. With the right dose, it also helps in relieving symptoms like nausea and vomiting.”
- “Types of Kratom used for opiate withdrawal. Since there are many strains and subspecies of Kratom, with various functions associated with the active ingredient, we can use different strains in the management of the various symptoms of withdrawal . . . Bali Blend – Bali red vein and 8x extract from Kratom Spot. It is the best Kratom for Opiate withdrawal . . . Sumatra Red Vein Powder. This strain of Kratom is most useful for the removal of opiate cravings . . . Green Thai Powder . . . Patients suffering from decreased libido or sexual dysfunction due to opiate withdrawal can take this strain and its effects last for up to 8 hours.”
- “Dose of Kratom for opiate withdrawal. At lower doses, Kratom affects the delta receptors, but at higher doses, it acts on the mu opioid receptors . . ..”

In addition to claims on your website, claims observed on your social media sites that establish the intended use of your products include, but may not be limited to, the following:

https://www.facebook.com/kratomspotonline:

- “Kratom Spot October 26, 2017. The federal government just declared the opioid crisis a public health emergency. Positive news for kratom as a result. Kratom is an all natural alternative...”

The claims on your website and social media sites establish that your kratom products are drugs under section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease—in particular, for opiate withdrawal and addiction.

Your kratom products are also “new drugs” under section 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Under section 505(a) of the FD&C Act, 21 U.S.C. 355(a), new drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA. No approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355(a), is in effect for these products. Accordingly, the introduction or delivery for introduction into interstate commerce of these products violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

Section 503(b)(1) of the FD&C Act, 21 U.S.C. 353(b)(1), identifies criteria for determining the prescription status of a product. Your above-mentioned kratom products are prescription drugs as defined in section 503(b)(1)(A) of the FD&C Act, 21 U.S.C. 353(b)(1)(A), because in light of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs.

Your above-mentioned kratom products are intended for the treatment or cure of opioid addiction and withdrawal symptoms, and/or other conditions that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. A drug is misbranded undersection 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), if the drug fails to bear adequate directions for its intended use(s). “Adequate directions for use” is defined in 21 CFR 201.5 as “directions under which the layman can use a drug safely and for the purposes for which it is intended.” Because the conditions for which your above-mentioned kratom products are intended require the supervision of a practitioner licensed by law to administer such drugs, adequate directions cannot be written so that a layperson can use your products safely. Thus, your kratom products’ labeling fails to bear adequate directions for their intended uses, which causes the products to be misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your marketed products. You are responsible for investigating and determining the causes of the violations identified above 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

and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct 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, 10903 New Hampshire Avenue, WO51, Silver Spring, MD 20993-0002 or by email to FDAADVISORY@fda.hhs.gov.

Sincerely,
/S/
Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

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