WARNING LETTER

Revibe, Inc.

MARCS-CMS 553137 — MAY 18, 2018

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Recipient:

Augustine Hanger
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United States

Issuing Office:

Center for Drug Evaluation and Research
United States

10903 New Hampshire Avenue
Silver Spring, MD 20993

May 18, 2018

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

Augustine Hanger
Revibe, Inc.
4141 Pennsylvania Street #201
Kansas City, MO 64111

WARNING LETTER

Dear Mr. Hanger,

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at https://buykratombulkusa.com in April

2018 and has determined that you take orders there for products “50x Black Diamond Extract,” “Gold Bali Kratom,” “Green Bali,” “Green Borneo Kratom,” “Green Horn Kratom,” “Green Indo,” “Green Maeng Da Kratom,” “Green Sumatra,” “Green Thai Kratom,” “Kratom Capsules,” “Lucky 7,” “Red Bali Kratom,” “Red Borneo,” “Red Horn,” “Red Maeng Da Kratom,” “Red Sumatra,” “Red Thai,” “Red Vein Indo,” “Super Elephant,” “Super Green Malay Kratom,” “Super Indo,” “White Bali,” “White Borneo,” “White Horn,” “White Maeng Da Kratom,” “White Sumatra,” “White Thai,” and “Yellow Vietnam Kratom,” all of which you claim to contain kratom. 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 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 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 and Misbranded Drugs

The claims on your website establish that the above-listed 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 articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Examples of claims observed on your website https://buykratombulkusa.com that establish the intended use of your kratom products as drugs include, but may not be limited to, the following:

On a page of your website titled “Kratom Colors Explained”:

- “Red Kratom helps the individual to fight against stress and anxiety issues.”
- “People who are suffering from insomnia can also use it as a sleeping aid.”
- “Red kratom is a great painkiller for stressed muscles, joint pains, and arthritis.”
- “It is best suggested for those who are suffering from depression . . .”

On a page of your website titled “Kratom: An alternative to painkiller”:

- “it works for all kinds of pain, like back pain, arthritis, sore tendons, scoliosis . . .”
- “The best strain to be used as a painkiller is either Red Bali or Maeng Da Kratom.”

On a page of your website titled “TOP 10 POSITIVE AND ADVERSE EFFECTS OF KRATOM”:

- “It can . . . be used by patients suffering from depression . . .”
- “Kratom, like any other pain killer, relieves temporary or even chronic pain.”
- “This plant can relieve headaches, vascular pain, arthritic pain, muscle pain among others.”
- “Kratom can be used as a remedy for stroke-related ailments and condition as it is a powerful antioxidant that works to reduce neuron damage.”
- “It can . . . help in lowering blood pressure.”
- “Kratom is also said to have elements that control blood sugar level in the body for diabetic patients.”
- “Kratom can be used to ease Opiate withdrawal. This is useful for those who would want to cut back on the usage of opiate [*sic*]without experiencing much of the withdrawal effects.”

On a page of your website titled “Kratom for treatment of arthritis pain”:

- “It’s not an exaggeration that it cures chronic pains.”
- “It is said, that kratom is very effective against cancer.”

- “It is also very effective for a handful of other conditions, like 93% for a migraine, 92% for back pain, 90% for Osteoarthritis and 90% for Neuropathy.”

On a page of your website titled “Kratom as an antioxidant and antibacterial”:

- “it’s been theorized it may possibly attenuate Type 2 diabetes.”
- “could be promising antioxidant and anticancer . . .”

On a page of your website titled “Best Red Strain for Pain Relief”:

- “The first option to get rid of the pain is using Bali and Borneo kratom. This sort of strain is recommended for people who suffer from joint issues as well as from cancer pain.”
- “The next option to relieve the body pain is Maeng de Kratom. This kind of strain is reccomendable [*sic*] for those who have the problem with chronic pain, arthritis or cancer.”
- “There is also a white sort of this powder called White Indo Vein which is perfect for people who suffer from fatigue for fibromyalgia.”

On a page of your website titled “How to Detox with Kratom”:

- “Mitragynine is known to be an opioid agonist because it has an attraction for the brain’s opioid receptors.”
- “So, when a person stops taking any drug, take, for example, heroin, Kratom will aid in minimizing the withdrawals.”
- “Kratom doesn’t only help the body with illnesses; it also helps with any symptoms of withdrawal. With the right dosage . . . you will surely be able to eliminate your drug dependency completely.”

On a page of your website titled “Current scientific research on kratom”:

- “Natives used it as an antidiarrheal, antidepressant and pain reliever . . .”
- “Kratom has also been looked into as a possibly remedy for opioid related withdrawal syndrome and as a potential alternative to addictive and potentially lifethreatening [*sic*] opiate based medicines in general.”
- “may be of possible use to those living with PTSD . . .”
- “Kratom may even be a potential adjunctive or complementary therapy in an anti-cancer and anti-tumor regimen.”

The claims on your website 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, including for opioid 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 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 fail 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 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 assure that you comply 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 that you have taken to correct the 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 actions 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. (mailto:FDAADVISORY@fda.hhs.gov)

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

cc:

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