Front Range Kratom - Warning Letter - Letter Issued: 05/18/2018

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Delivery Method:
Overnight Delivery

Recipient:
Recipient Name
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Front Range Kratom
2790 South Havana Street, Unit T
Aurora, CO 80014
United States

Issuing Office:
Center for Drug Evaluation and Research
United States

10903 New Hampshire Avenue
Silver Spring, MD 20993

May 18, 2018

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Gregory Todd Schulte
Front Range Kratom
2790 South Havana Street, Unit T
Aurora, CO 80014

RE: 552391

Dear Mr. Schulte:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.frontrangekratom.com in April 2018 and has determined that you take orders there for various kratom products, including but not limited to, "Maeng Da Red Vein Powder," "Maeng Da White Vein Capsules," "Maeng Da White Vein Powder," "Red Bali Kratom Powder," "Liquid Kratom Red Maeng Da Enhanced Pain Formulation," "Bali White Vein Kratom Powder," "Maeng Da Green Vein Capsules," "Maeng Da Green Powder,

" "Bali Green Vein Powder," and "Maeng Da White Energizing Formula." We have also reviewed your social media websites at www.facebook.com/FrontRangeKratom and www.twitter.com/frorangekratom. 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.

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 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.frontrangekratom.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 "Facts and Questions" from the February 6, 2018 "New Customers" posting:

- "I have a lot of people coming in and asking about how Front Range Kratom in Denver could help them with various things. For me, the two things I think kratom works the best for are pain and to help people get through some of the post acute withdrawl (*sic*) symptoms they get when they come off of their pain medications."
- "Certainly kratom is useful for pain - myself and everyone else on the internet can attest to that. But as someone who has experienced the withdrawl (*sic*) type symptoms from coming off of opiates, I can tell you that getting through the depression . . . is the hardest part. I have found personally that kratom is useful for this and you can read on reddit and everywhere else on the internet other people's experiences."

On the page of your website titled "Red Bali Kratom Powder":

- "Bali red vein kratom powder has been used for centuries for the treatment of pain and opiate addiction in the far east."

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/frontrangekratom:

- March 18 posting: "Along with helping drug addiction, the health benefits of kratom leaves include their ability to lower blood pressure, relieve pain, boost metabolism, increase sexual energy, improve the immune system, prevent diabetes, ease anxiety, eliminate stress, and induce healthy sleep."
- March 11 posting: "Great post from ER doc on how Kratom is vital to helping people with opiate addiction"
- February 20 posting: "Chris Bell: Kratom Is the Cure for the Opioid Epidemic"

https://www.twitter.com/frorangekratom:

- March 11 posting: "How Kratom is helping with opiate addiction from someone on front lines"

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 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/or other conditions that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. A drug is misbranded under section 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 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

Cc: Front Range Kratom
8022 East Bucknell Place
Denver, CO 80231

