KratomNC - Warning Letter - 05/16/2019

Delivery Method: Overnight Delivery Product: Drugs

Recipient:

Recipient Name
Mike Davies
KratomNC
925 S. Kerr Ave. Suite M2
Wilmington, NC 28403-4335
United States

Issuing Office:

Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993
United States

WARNING LETTER

VIA OVERNIGHT DELIVERY

RETURN RECEIPT REQUESTED

May 16, 2019

Mike Davies

Kratom NC

925 S. Kerr Ave. Suite M2

Wilmington, NC 28403-4335

RE: 576964

Dear Mike Davies:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the internet address ttp://kratomnc.com in May 2019 and has determined that your website provides a telephone number that customers can call to order various kratom products, including but not limited to, "Green Bali Powder," "Red Indo Powder," "Gold Bali Powder," "White Indo Powder" and "Super White Powder." 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 (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 of opioid addiction. 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

Claims on your website establish that your kratom products, including "Green Bali Powder," "Red Indo Powder, " "Gold Bali Powder," "White Indo Powder" and "Super White Powder," are drugs as defined by 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, including opiate addiction, and/or because they are intended to affect the structure or function of the body. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the FD&C Act.

Examples of claims observed on the website, ttp://kratomnc.com, that establish the intended use of your kratom products include, but may not be limited to the following:

- "Kratom is used for energy, to increase attention/focus, to relax, and also to treat pain and addiction. Here is just some of what our customers have used kratom to treat . . . Chronic Pain, Migraines, Opiate Addiction, ADHD/ADD, Anxiety, Depression, Arthritis, Insomnia and much more!"
- "Red Vein Kratom . . . is generally used for it's *[sic]* sedation and pain killing effects. It's better for treating pain & for relaxation."
- "Green Vein Kratom . . . used more for focus/energy . . .."
- "Greens . . . are great for ADHD and depression . . ."

Your kratom products, "Green Bali Powder," "Red Indo Powder," "Gold Bali Powder," "White Indo Powder" and "Super White Powder," 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, 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).

In addition, your kratom products, "Green Bali Powder," "Red Indo Powder," "Gold Bali Powder," "White Indo Powder" and "Super White Powder," are misbranded under 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). According to section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), a drug is misbranded if, among other things, it fails to bear adequate directions for use. "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." As previously noted, your kratom products are intended for the treatment of opioid addiction as well as for other

conditions that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Because the conditions for which your kratom products are intended require the supervision of a practitioner licensed by law to administer drugs for such conditions, adequate directions cannot be written so that a layperson can use your products safely. Moreover, your kratom products are not exempt, under 21 CFR 201.100(c)(2) or 201.115, from the requirements that their labeling bear adequate directions for use because no FDA-approved applications are in effect for your products. 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

