WARNING LETTER

Cali Botanicals, LLC

MARCS-CMS 575320 — JUNE 11, 2019

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

Delivery Method:
Overnight Delivery

Product:
Drugs

Recipient:
Mr. Justin Martinez
Cali Botanicals, LLC
500 Sibley Street
Folsom, CA 95630
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

June 11, 2019

Cali Botanicals, LLC

Mr. Justin Martinez
500 Sibley Street
Folsom, CA 95630

11335 Sunrise Gold Cir H
Rancho Cordova, CA 95742

RE: 575320

Dear Mr. Martinez:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.calibotanicals.com in March 2019 and has determined that you take orders there for various kratom products, including but not limited to, "12 Gram Kratom Powder Samples," "Borneo Yellow Vein Kratom," "Bali Kratom Powder," "Cali's Best Premium Powder Mix," "Cali's Premium Special Reserve Kratom Powder," "Enhanced Maeng Da Capsules," "Green Malay Kratom Caps," "Kratom Capsule Samples," "Full Spectrum 50x Kratom Tincture," "Super Enhanced Bali Kratom," and "Super Enhanced Maeng Da Kratom," hereinafter referred to as your kratom products. We have also reviewed your social media websites at www.facebook.com/calibotanicals and www.twitter.com/calibotanicals. 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 (/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 forgo 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 the above-mentioned products 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 withdrawal and 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 where you take orders, www.calibotanicals.com, that establish the intended use of your kratom products include, but may not be limited to the following:

On the webpage titled "Kratom FAQs":

- "Kratom acts as a μ-opioid receptor-like morphine."
- "Kratom…in low to moderate doses it will commonly be stimulating, and in large doses, it has a more sedative effect."
- "As a sedative, used in higher doses, an individual will experience an analgesic effect along with euphoria, a lower sensitivity to pain both physically and emotionally, relaxation, anti-depression, and anti-anxiety."

- “Usage: It is for the management of chronic pain, as well as recreationally.”

On the webpage titled “What is Kratom”:

- “In small quantities, [kratom] causes a stimulant-affect. Other uses include the treatment of diabetes, diarrhea, and fever.”
- “[Kratom] aid[s] in leveling the often deadly risks of opiate withdrawal as well as its use an antidiabetic by lowering blood sugar levels.
- “Another very enticing use for Kratom is that of an aphrodisiac, used to increase stimulation and enhance male performance in the bedroom.”
- “Kratom has essential uses in combating opiate addiction and the harrowing withdrawal that comes with trying to kick the habit.”

On the webpage titled “Buy Bali Kratom Powder Online”:

- “The Bali strain’s analgesic and sedative alkaloids have helped thousands of people in search of a relaxing and pain relieving strain.”

On the webpage titled “Kratom Benefits”:

- “Maybe you’re battling addiction or can’t seem to sleep well? If any of these things are right for you, consider giving kratom a try.”
- “[Kratom] leaves can…eliminate the feeling of stress, assist in the battle of addiction, and relieve anxiety.”
- “Kratom leaves have long been known to alleviate opioid addiction…addicts can wean themselves off of their addictions by replacing their drugs with kratom. It has similar effects as opioids, but without the same dependency. Kratom also helps with the withdrawal symptoms addicts experience, making the process of overcoming addiction slightly easier.”
- “Some researchers have even claimed that kratom can protect you against cancer!”
- “Consumption of kratom can reduce pain and swelling to an injury.”

On the webpage with the Blog titled, “Red Veins”:

- “[Red Vein Kratom] produces more of a pain relieving and euphoric effect.”
- “[R]ed vein Bali has a more potent sedative type of effect, while the Red Thai is considered more stimulating.”
- “Both of the [Thai and Bali strains] make for quite effective alternatives to opiates and can be used for alleviating depression and anxiety or used as a sleep aid.”

On the webpage with the Blog titled, “Why Kratom Really Works”:

- “[K]ratom is able to reduce the pain levels that reach the brain in a way that’s very similar to opioid drugs. This is why some addicts turn to kratom as a means of treating their opioid addiction.”

On the webpage with the Blog titled, “Cali Botanicals Take on Kratom vs CBD”:

- “Kratom…works quite well when relieving something called nociceptive pain.”
- “[Kratom] has very mild, opioid-like effects in larger doses. When taken this way, kratom is seen as life-saving by former addicts, who found kratom to be the only way they could overcome their addictions. Between kratom and CBD, kratom is considered the better opioid substitute (https://www.kratomnews.org/cbd-vs-kratom/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).”
- “Both [CBD and kratom] are natural painkillers, they’ve become alternatives to opioids and prescription drugs.”

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

www.facebook.com/calibotanicals:

- Post by Cali Botanicals, dated May 8, 2018
  “I have some chronic pain and kratom is my preferred method of dealing with it.”

- Post by Cali Botanicals, "What is Kratom," dated December 6, 2017
  "Kratom is frequently used as a natural alternative to treat depression, anxiety, addiction, diabetes, chronic pain and fatigue. . . . Kratom has been reported to have taken the place of brand name drugs like Hydrocodone or Oxycodone for individuals, all the way to weaning people off of Heroin."

www.twitter.com/calibotanicals:

- Post by **(b)(6)**@calibotanicals, dated December 12, 2018, "…I have multiple physical ailments and I refused to take narcotics… This stuff helps my pain so much it's unreal…"

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, 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 are misbranded under section 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, a drug is misbranded if, among other things, it 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." As previously noted, your kratom products are intended for the treatment or cure of opioid addiction and withdrawal symptoms 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