WARNING LETTER

Chillin Mix Kratom

MARCS-CMS 559280 — SEPTEMBER 04, 2018

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Recipient:
Chillin Mix Kratom
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

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

September 4, 2018

Mr. Billy Christian
(b)(6)

RE: 559280

Dear Mr. Christian:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.chillinmixkratom.com in July 2018 and has determined that you take orders there for various kratom products, including but not limited to, “Maeng Da Powder,” “White Vein Powder,” “Red Vein Powder,” “Green Malaysian Powder,” “Maeng Da Kratom Capsules,” “Chillin Mix Kratom Maeng Da Capsules,” “Chillin Mix Kratom Maeng Da Powder,” “Chillin Mix Kratom Extract Capsules,” and “Mitragyna Speciosa All Natural Botanical Extract Capsules.” 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

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.chillinmixkratom.com, that establish the intended use of your products include, but may not be limited to the following:

- "Kratom can render both mildly stimulating effects and mildly relaxing effects depending upon the measurement used. At smaller amounts, the effects tend to be slightly more stimulating; and at larger amounts, the effects tend to be more relaxing."
- "Some [kratom users] have reported an increase in focus, attentiveness, and social confidence resulting from the responsible use of kratom."
- "Due to the rise in opium costs and the discovery that kratom could relieve opium withdrawals, many users turned to kratom as a means to cure their addiction."
- "It has been long reported that kratom has been used to treat a myriad of ailments including but not limited to: diarrhea, depression, diabetes, obesity, high blood pressure, stomach parasites, diverticulitis, anxiety, alcoholism, and opiate withdrawal."

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).

In addition, your kratom products are misbranded under 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), because they lack adequate directions for use. 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