Sunshine Trading Company, Inc. dba Nova Tea and Nova Kratom - Warning Letter - Letter Issued: 07/03/2023

CMS 660633

Delivery Method:
Via Email
Product:
Drugs

Recipient:
Recipient Name
Joshua Miller
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Issuing Office:
Center for Drug Evaluation and Research | CDER
United States

WARNING LETTER

July 3, 2023

1530 S Nevada Ave.
Colorado Springs, CO 80905

RE: 660633

Dear Joshua Miller:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at www.novakratom.com in June 2023 and have determined that you take orders there for kratom products such as varieties of Red Vein Kratom, White Vein Kratom, Green Vein Kratom, and Yellow Vein Kratom including "Green Maeng Da Kratom Powder," "Green Malay Kratom Powder," "Red Bali Kratom Powder," "Yellow Vietnam Kratom Powder," "White Borneo Kratom Powder," and a mixture of kratom strains. Based on our review, these products are unapproved new drugs under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). As explained further below, introducing or delivering these products for introduction into interstate commerce violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

The Department of Health and Human Services (HHS) has determined that a public health emergency exists nationwide involving the opioid crisis.[1] You market kratom products for 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

Your kratom products are drugs under 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, and/or intended to affect the structure or any function of the body. Examples of claims observed on your website that establish the intended use of your products as drugs include, but may not be limited to, the following:

On your firm's webpage https://novakratom.com/news/kratom-powder-vs-kratom-capsules/:

- "What Are The Benefits of Using Kratom? . . . Kratom contains alkaloids such as mitragynine and 7-hydroxymitragynine that acts [sic] on the opioid receptors to produce opioid-like effects. It can help relieve pain, improve mood, increase concentration or focus, relaxation, and more. Some users with opioid withdrawal have also reported that kratom helps eases [sic] their symptoms."

On your firm's webpage https://novakratom.com/news/kratom-vs-kava/:

- "Although kratom is not an opiate, it produces effects similar to opiate drugs. For this reason, kratom is often sought after for its analgesic effects. It is also used by those addicted to opioids to help with their withdrawal symptoms. Like opioids, users can develop a tolerance and addiction to kratom."

On your firm's webpage https://novakratom.com/news/maeng-da-kratom-vs-bali-kratom/:

- "Kratom is well-known for its ability to offer pain relief as it contains alkaloids such as mitragynine and 7-hydroxymitragynine that acts [sic] as opioid receptor agonists to produce opioid-like effects. This is why many patients with chronic pain turn to kratom as they no longer want to be entirely dependent on prescription pain medication."
- "The most active alkaloid in maeng da kratom is mitragynine, a compound best used to relieve chronic pain by acting on opioid receptors."
- "Bali kratom is also great for those experiencing pain, anxiety, depression, or have withdrawal symptoms."

On your firm's webpage https://novakratom.com/news/red-vs-green-kratom/:

- "Red Bali is a versatile strain and is best used for relaxation, pain relief, and opiate withdrawal."
- "Another potent strain, red Sumatra can help promote undisturbed rest and reduce anxiety, stress, and depression."

On your firm's webpage https://novakratom.com/news/strongest-kratom/:

- "Kratom Benefits . . . Energy Boost . . . Mental Clarity and Focus . . . Mood Elevation . . . Relaxation . . . Pain Relief . . . Opiate Withdrawal"
- "Kratom is best for all types of pain ranging from mild to severe, acute or chronic. Some of the disorders kratom can help with include fibromyalgia, rheumatic arthritis, autoimmune disease, multiple sclerosis, cancers, systemic lupus erythematosus, connective tissue disorders, and more."

On your firm's webpage https://novakratom.com/strains/white-vein-kratom/:

- "Some white strains maintain an analgesic effect, while others deliver a powerful energy boost. A few varieties can even be used to achieve an opioid-like state of euphoria . . .."

Your kratom products are not generally recognized as safe and effective (GRASE) for their above referenced uses and, therefore, are "new drugs" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C. 355(a) and 331(d). There are no FDA-approved applications in effect for your kratom products. Introduction or delivery for introduction of these products into interstate commerce without an

approved application violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations 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, including FDA regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and injunction.

Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to correct these 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, by email to FDAAdvisory@fda.hhs.gov.

Sincerely,
/S/
Jill Furman
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Cc:
(b)(4)

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1 Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued October 26, 2017, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

Content current as of:

07/11/2023

Regulated Product(s)

- Drugs

