WARNING LETTER

Shot of Joy LLC

MARCS-CMS 665936 — SEPTEMBER 25, 2023

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Delivery Method:
Via Email
Product:
Drugs

Feedback

Recipient:
James B. Carty
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United States

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Issuing Office:
Center for Drug Evaluation and Research | CDER
United States

WARNING LETTER

September 25, 2023

RE: 665936

Dear James B. Carty:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at https://shotofjoy.com/ in September 2023 and determined that you take orders there for various Shot of Joy brand kratom and kava products, including “Classic – Kratom & Kava Shot,” “Relax – Kratom & Kava Shot,” “Focus – Kratom Shot,” “Kava Only Shot,” “Kratom Gummies,” and “Classic Kratom & Kava Gummies.” 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 and kava 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 are not limited to, the following:

On your webpage entitled, “Kratom for Anxiety and Depression: Does It Work”; https://shotofjoy.com/blogs/kratom/kratom-for-anxiety:
• “In addition to depression and anxiety, it is believed that kratom can cure the following conditions[,] Tiredness hypertension[,] Opioid addiction[,] Withdrawal symptoms[,] Post-traumatic stress disorder (PTSD)”
• “Fighting Depression and Anxiety with Kratom[,] Kratom has been widely used by people around the world to relieve stress and other symptoms of depression . . .”

On your webpage entitled, “10 Awesome Kava Benefits to Know”; https://shotofjoy.com/blogs/kava/kava-benefits?_pos=1&_psq=10%20%20awe&_ss=e&_v=1.0:
• “Here are ten amazing kava benefits you should be aware of . . . May Alleviate ADHD Symptoms[,] Kava may be beneficial to people who suffer from attention deficit hyperactivity disorder (ADHD). In a small clinical trial, children with ADHD who took kava supplements outperformed those who took a placebo in terms of attention, hyperactivity, and impulsivity. . . . May help with depression symptoms[,] Kava has been studied for its ability to help with depression symptoms. Kava was found to be effective in reducing depression symptoms in people with major depressive disorder in a clinical trial. . . . May Help with Cardiovascular Health[,] Kava may help with cardiovascular health by lowering blood pressure and increasing cholesterol levels. In a clinical trial, people with high blood pressure who took kava supplements had lower blood pressure than those who took a placebo.”

On your webpage entitled, “Kava Effects on Brain: Beginner’s Guide”; https://shotofjoy.com/blogs/kava/kava-effects-on-brain:
• “Neuroprotection: Kava has preventive properties against strokes. Two of Kava's constituents, dihydromethysticin and methysticin, have similar potency to the Alzheimer's disease treatment Memantine.”
• “Antidepressant effects have also been observed in kava preparations. Several of the studies establishing this antidepressant effect also revealed that Kava posed no safety issues at the levels and period evaluated. Unlike a number of well-known antidepressants. Kava has also been demonstrated to improve cognition and focus. In one study, researchers indicated that Kava's capacity to prevent the reuptake of noradrenaline in the prefrontal cortex may be responsible for its cognitive enhancing effects. Moreover, Kava protects and may possibly treat a variety of cancers. One of the components of Kava, Flavokawain B, decreases prostate tumor growth and prevents malignancy, according to research.”

On your webpage entitled, “Authentic Polynesian Kava Drink Recipes”; https://shotofjoy.com/blogs/kava/polynesian-drinks:
• “Beyond its cultural significance, kava is known for its medicinal properties. The active compounds called kavalactones found in the kava root contribute to its . . . depression-relieving effects.”

Your kratom and kava 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 and kava 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).

The violations cited in this letter are 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 any 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/

CAPT Tina Smith
Acting Director
Office of Unapproved and Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

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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.

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