WARNING LETTER

Royal Diamond Imports, Inc.

MARCS-CMS 709540 — JUNE 25, 2025

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Delivery Method:

Via Email

Product:

Drugs
Food & Beverages

Recipient:

Amir Surani
Rafeeq Manjiyani
Royal Diamond Imports, Inc.
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United States

Sales@roxytabs.com (mailto:Sales@roxytabs.com)

Issuing Office:

Human Foods Program
United States

June 25, 2025

WARNING LETTER

CMS # 709540

Dear Messrs. Surani and Manjiyani:

This letter concerns your products Roxy Instamix Complex Alkaloid Drink Mix (in passion fruit flavor) and ROXY 7-OH tablets, (15mg and 16mg), ROXY+ 7-OH 20mg tablets, and ROXY XL 7-OH 60mg tropical flavor tablets (hereinafter “your 7-OH Tablets”), offered in different flavors and/or package sizes. Your product labeling for these products represent that

the products contain 7-hydroxymitragynine (7-OH).[1] As explained further below, introducing or delivering these products for introduction into interstate commerce violates the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

FDA has observed a proliferation of products containing 7-OH, and has serious concerns about products containing 7-OH. The concerns include the following: 1) 7-OH products have not been evaluated by FDA for safe use; 2) FDA has received adverse event reports associated with 7-OH containing products; and 3) 7-OH has been reported to have opioid-like effects.

Adulterated Human Foods: Unsafe Food Additive

Based on a review of your product labeling, your Roxy Instamix Complex Alkaloid Drink Mix, in passion fruit flavor, is a multi-ingredient food that contains 7-OH that is supplied by the addition of kratom extract to this food.

As defined in section 201(s) of the Act (21 U.S.C. 321(s)), the term "food additive" refers to any substance the intended use of which results in it becoming a component of any food, unless the substance is generally recognized as safe (GRAS) among qualified experts under the conditions of its intended use, or unless the substance meets a listed exception.[2]

Food additives require premarket approval based on data demonstrating safety. Any food additive that has not been approved for its intended use in food is deemed to be unsafe under section 409(a) of the Act (21 U.S.C. 348(a)) and causes the food to be adulterated under section 402(a)(2)(C)(i) of the Act (21 U.S.C. 342(a)(2)(C)(i)). Introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the Act (21 U.S.C. 331(a)).

There is no food additive regulation that authorizes the use of kratom extract in food. We are not aware of any information to indicate that kratom extract is the subject of a prior sanction (see 21 CFR Part 181). Furthermore, we are not aware of any basis to conclude that kratom extract is GRAS for use in conventional foods. FDA's regulations in 21 CFR 170.30(a)-(c) describe the criteria for eligibility for classification of a food ingredient as GRAS. The use of a food substance may be GRAS based on either scientific procedures or, for a substance used in food before 1958, through experience based on common use in food (see 21 CFR 170.30).

We know of no basis for general recognition of safety for kratom extract based either on scientific procedures or common use in food prior to January 1, 1958. Based on our review of published scientific literature, existing data and information do not provide an adequate basis to conclude that the use of kratom extract in food meets the criteria for GRAS status. Therefore, based on our review, the use of kratom extract in conventional food does not satisfy the criteria for GRAS status under 21 CFR 170.30. Moreover, some of the available data raise serious concerns about potential harm associated with kratom extract. Our review of published scientific literature and adverse event reports related to consumption of kratom and kratom-derived products raise a number of safety concerns, including liver toxicity, cardiovascular toxicity, seizures, gastrointestinal distress, respiratory depression, addiction, withdrawal symptoms, and death. It's not clear from available evidence whether all of these effects were due to mitragynine or 7-OH (i.e., two of the main alkaloids found in kratom) in these products. Although 7-OH is a minor component of kratom, it is a more potent inducer of opioid-like effects than the primary kratom alkaloid, mitragynine, and mitragynine converts to 7-OH in the body. Because of this, products containing enhanced levels of 7-OH are of particular concern because we anticipate an increased risk of adverse effects as the dose of 7-OH increases.

FDA is not aware of any other exception to the food additive definition that would apply to kratom extract for use as an ingredient in a conventional food. Therefore, kratom extract when added to a conventional food is a food additive under section 201(s) of the Act and is subject to the provisions of section 409 of the Act. Under section 409, a food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. Kratom extract is not approved for use

in any conventional food. Food containing an unsafe food additive within the meaning of section 409 is adulterated within the meaning of section 402(a)(2)(C)(i) of the Act. Therefore, your Roxy Instamix Complex Alakaloid Drink Mix (in passion fruit flavor) is adulterated within the meaning of section 402(a)(2)(C)(i) of the Act because it bears or contains an unsafe food additive. The introduction or delivery for introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the Act (21 U.S.C. 331(a)).

Unapproved New Drugs

Based on our review of your website, www.roxytabs.com, your 7-OH Tablets are drugs under section 201(g)(1) of the 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 from your website that provide evidence of the intended use of your products as drugs include, but may not be limited to, the following:

On your ROXY XL 7-OH 60mg tropical flavor tablets webpages[3]:
• “Each 60mg tablet delivers potent, full-bodied relaxation”

On your website homepage https://roxytabs.com:
• Your webpage has a graphic of your ROXY+ 7-OH 20mg tablets floating in the clouds with the statement “Get ready to elevate your experience with ROXY+ . . . delivering potent, and full-bodied relaxation.”
• “Find Your Calm with Roxy . . . Roxy Kratom Tablets can help soothe your nerves and bring a peaceful calm, much like the tranquility of a quiet afternoon in nature. Perfect for unwinding after a long day, these tablets promote relaxation and stress relief.”
• “Experience Enhanced Mood Naturally . . . Consuming Roxy Kratom Tablets in appropriate amounts can uplift your mood, making you feel happier and more appreciative of life’s simple joys, much like enjoying a peaceful moment with a warm cup of coffee.”

On your “FAQs” webpage https://roxytabs.com/pages/faq:
• “Q: How does 7-Hydroxymitragynine work?
A: 7-Hydroxymitragynine mainly functions as a partial agonist of brain receptors, which results in its distinct effects.”
• “Q: What are the potential benefits of 7-Hydroxymitragynine?
A: Some users of kratom products with 7-Hydroxymitragynine report experiencing relief or an energy boost, but further research is necessary to fully comprehend its effects.”

On your “About Us” webpage https://roxytabs.com/pages/roxy:
• “Why Choose Roxy Tabs? . . . Consistency and Purity: Roxy Kratom are produced with the highest standards of quality control, ensuring each tablet delivers a precise dose of 16mg of 7-Hydroxymitragynine. This consistency is key to achieving desired effects such as enhanced mood, increased energy, and pain relief without the variability found in loose leaf or powdered products.”
• “Powerful Effects: With around 2% active 7-hydroxymitragynine alkaloid, Roxy Kratom Tablets are among the most potent kratom products available on the market. Users can expect powerful effects that enhance mood, improve sociability, and provide significant relaxation and pain relief, depending on the dosage.”
• “Potential Benefits . . . Enhanced Mood . . . Increased Focus and Energy . . . Pain Management . . . Stress and Anxiety Relief . . . Improved Sleep”
• “Roxy Kratom Tablets represent a significant advancement in herbal supplementation, providing a powerful, consistent, and convenient option for enhancing well-being. By adhering to recommended dosages and guidelines, users can safely enjoy the myriad benefits that kratom has to offer. Whether seeking relief from pain, a boost in energy, or a natural way to manage anxiety, Roxy Tabs provide a trustworthy solution to improve quality of life.”

On your “Product Details” webpage https://roxytabs.com/pages/product-details:
• “Roxy Kratom Tablets are expertly formulated to provide a potent dose of kratom's active alkaloids, specifically 7-hydroxymitragynine, which is known for its ability to enhance mood, alleviate pain, and increase energy levels. Each tablet is designed to deliver a consistent and effective experience to support daily well-being.”

Additionally, your website contains evidence of intended use in the form of personal testimonials recommending or describing the use of your products for the treatment of disease and/or to affect the structure or function of the body. Examples of such testimonials include, but are not limited to, the following:

• “I have a very painful chronic disease. Unfortunately my pain management doctor seems to have capped my dosage of my standard pain medication at an insufficient level. If I didn’t have kratom I don’t know what I’d do. Roxy is the best product I’ve tried.” [From the Customer Reviews section of the ROXY+ 7-OH 20mg tablets product webpage https://roxytabs.com/products/roxy-20mg-7-hydroxymitragynine-30-flavored-tablets-jar]
• “I’m sharing this because I've discovered an incredible effect that has truly transformed my experience. I chew a half tablet, and within about 15 minutes, the pain fades away, replaced by pure relaxation without any grogginess. This is truly exceptional.” [From the Customer Reviews section of the ROXY 7-OH 16mg tablets product webpage https://roxytabs.com/products/roxy-16mg-7-hydroxymitragynine-2-count-blister-pack-tablets]

Your 7-OH Tablets are not generally recognized as safe and effective (GRASE) for their above referenced uses and, therefore, these products are “new drugs” under section 201(p) of the Act (21 U.S.C. 321(p)). Subject to certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without an approved application from FDA in effect, as described in sections 301(d) and 505(a) of the Act (21 U.S.C. 331(d) and 355(a)). There are no FDA-approved applications in effect for your 7-OH Tablets. Accordingly, these products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the Act (21 U.S.C 355(a) and 331(d)).

Conclusion

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 15 working days of receipt of this letter, of the specific steps you have taken to address 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 cannot complete corrective actions within 15 working days, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration.

Your written reply should be directed to Kimberly Dutzek, Compliance Officer, United States Food and Drug Administration, Human Foods Program, Office of Enforcement, 5001 Campus Drive, College Park, Maryland 20740-3835 or via email at HFP-OCE-DietarySupplements@fda.hhs.gov. Please reference CMS #709540 on any submissions and within the subject line of any emails to us. If you have any questions, you may email at HFP-OCE-DietarySupplements@fda.hhs.gov.

Sincerely,
/S/

Ann M. Oxenham
Director, Office of Enforcement
Office of Compliance and Enforcement
Human Foods Program
Food and Drug Administration

/S/

Jill Furman, J.D.
Director
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

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1 7-hydroxymitragynine (7-OH) is also known as 7-OHMG, 7-HMG, 7OH-mitragynine, and on the market as 7-OH, or 7OH.

2 Under section 201(s) of the Act (21 U.S.C. 321(s)), the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food, (2) pesticide chemicals, (3) color additives, (4) substances used in accordance with a "prior sanction," i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the Act, the Poultry Products Inspection Act, or the Meat Inspection Act, (5) new animal drugs, and (6) dietary ingredients in or intended for use in a dietary supplement.

3 https://roxytabs.com/products/roxy-xl-60mg-7-hydroxymitragynine-5-tablets-blister-pack and https://roxytabs.com/products/roxy-xl-60mg-7-hydroxymitragynine-10-blister-pack-display