WARNING LETTER

Relax Relief Rejuvenate Trading, LLC dba RRR Trading or EDP Kratom

MARCS-CMS 709475 — JUNE 25, 2025

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

Delivery Method:
Via Email
Product:
Food & Beverages

Recipient:
Dustin Robinson and Ajaykumar Patel
Owners
Relax Relief Rejuvenate Trading, LLC dba RRR Trading or EDP Kratom
715 Armour Road, Apt. 712
Kansas City, MO 64116-3678
United States

general@edpkratom.com (mailto:general@edpkratom.com)

Issuing Office:
Human Foods Program
United States

United States

WARNING LETTER

June 25, 2025

RE: CMS 709475

Dear Messrs. Robinson and Patel:

This letter concerns your product EDP 7OH Mitragyna Speciosa Extract 50 mg shot. Your product labeling for this product declares 7-hydroxymitragynine (7-OH)[1] as an ingredient. As explained further below, introducing or delivering this product 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 Dietary Supplements

The labeling of your EDP 7OH Mitragyna Speciosa Extract 50 mg shot declares 7-OH as a dietary ingredient. Based on a review of your product labeling, the 7-OH in your EDP 7OH Mitragyna Speciosa Extract 50 mg shot is a "dietary ingredient" under section 201(ff)(1)(F) of the Act (21 U.S.C. 321(ff)(1)(F)). 7-OH is also a "new dietary ingredient" under section 413(d) of the Act (21 U.S.C. 350b(d)) because, to the best of FDA's knowledge, there is no information demonstrating that 7-OH was marketed as a dietary ingredient in the United States before October 15, 1994.

A dietary supplement is adulterated under section 402(f)(1)(B) (21 U.S.C. 342(f)(1)(B)) of the Act if it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Based on our evaluation of the relevant safety evidence, there is inadequate information to provide reasonable assurance that 7-OH does not present a significant or unreasonable risk of illness or injury. Therefore, your dietary supplements containing 7-OH are adulterated under section 402(f)(1)(B) of the Act. The introduction of such adulterated dietary supplements into interstate commerce is prohibited under section 301(a) of the Act. Moreover, available information on the use of 7-OH in products raises serious safety concerns.

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 #709475 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 Compliance and Enforcement

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