WARNING LETTER

Hydroxie, LLC

MARCS-CMS 709661 — JUNE 25, 2025

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

Delivery Method:

VIA EMAIL AND UPS

Product:

Drugs
Food & Beverages

Recipient:

Tim R. Shaw
Owner
Hydroxie, LLC
306 W El Norte Pkwy
STE N 92
Escondido, CA 92026
United States

support@hydroxie.com (mailto:support@hydroxie.com)

Issuing Office:

Center for Drug Evaluation and Research (CDER)
United States

Human Foods Program
United States

June 25, 2025

WARNING LETTER

RE: 709661

Dear Tim Shaw:

This letter is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the internet address www.hydroxie.com in May 2025 and has observed that your website offers various products that appear to contain 7-hydroxymitragynine (7-OH)[1] including Hydroxie 15mg 7-OH Tablets, Hydroxie Red 15mg Tablets, Hydroxie 30mg 7-OH Tablets, Hydroxie 15mg 7-OH Sublingual Strips, Hydroxie Red 15mg Sublingual Strips, Hydroxie 7-OH Shots, Hydroxie Red Shots, Hydroxie Free Sample, and Hydroxie Red Free Sample.[2] We have also reviewed your Instagram social media account at www.instagram.com/enjoyhydroxie/. Your Instagram social media account directs consumers to your https://shop.hydroxie.com website to purchase your products. As described below, your Hydroxie 15mg 7-OH Tablets, Hydroxie Red 15mg Tablets, Hydroxie 30mg 7-OH Tablets, Hydroxie 15mg 7-OH Sublingual Strips, Hydroxie Red 15mg Sublingual Strips, Hydroxie 7-OH Shots, Hydroxie Red Shots, Hydroxie Free Sample, and Hydroxie Red Free Sample products are unapproved new drugs introduced or delivered for introduction into interstate commerce in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a) and 331(d).

FDA has also determined that your Hydroxie 7-OH Drink Mix product, offered in various flavors, is marketed to contain 7-OH, and therefore is adulterated under section 402(a)(2)(C)(i) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(i), because it bears or contains an unsafe food additive. You can find the FD&C 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.

Unapproved New Drugs

Based on our review of your website, www.hydroxie.com, and social media account, www.instagram.com/enjoyhydroxie/, your Hydroxie 15mg 7-OH Tablets, Hydroxie Red 15mg Tablets, Hydroxie 30mg 7-OH Tablets, Hydroxie 15mg 7-OH Sublingual Strips, Hydroxie Red 15mg Sublingual Strips, Hydroxie 7-OH Shots, Hydroxie Red Shots, Hydroxie Free Sample, and Hydroxie Red Free Sample 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, and/or intended to affect the structure or any function of the body. Examples of claims observed on your website and social media account that establish the intended use of your above products as drugs include, but may not be limited to, the following:

On your blog post at https://hydroxie.com/blogs/news/9-ways-to-boost-your-mental-clarity:

- "7-Hydroxymitragynine acts primarily as a partial agonist of receptors in the brain. This activity leads to its unique effects. . .. Some users of products that contain 7-Hydroxymitragynine report feeling relief or a boost"

- "The Path to Mental Clarity . . . Your brain's capacity for improvement is remarkable, and with dedicated practice, you can achieve significant gains in mental clarity and cognitive function. Check out Hydroxie's full range of product offerings here and see which is best for your lifestyle."

On your blog post at https://hydroxie.com/blogs/news/how-to-have-more-energy-naturally-our-natural-energy-enhancement-guide:

- "Ready to explore natural energy enhancement? Start with our premium 7-OH products"

On your Instagram social media account at www.instagram.com/enjoyhydroxie/:

- May 20, 2025 post: "Hydroxie strips are ultra-concentrated – powerful by design . . . they're a simple way to empower your calm, focus, and clarity."

- May 16, 2025 post: "calm, clarity, & relief"

• May 13, 2025 post: “Hydroxie offers tablets, shots, sublingual strips, and drink mixes – each designed to empower you with relief, clarity, and calmness.”

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:

• “The amount of relief that I get for my Fybromyalgia and Osteoarthritis is amazing. One dose at bedtime give me pain relief thru most if [sic] the following day.” [From the Customer Reviews section of the Hydroxie 7-OH Shots product webpage https://hydroxie.com/products/hydroxie-7-oh-shot]

• “I LIV [sic] IN PAIN DAILY ALONG WITH SEVERE DEPRESSION. THIS HELPED BRING BE [sic] BACK TO LIFE.” [From the Customer Reviews section of the Hydroxie 15mg 7-OH Tablets product webpage https://hydroxie.com/products/hydroxie-15mg-7-oh-tablets]

• “These have helped my anxiety so much” [From the Customer Reviews section of the Hydroxie 15mg 7-OH Tablets product webpage https://hydroxie.com/products/hydroxie-15mg-7-oh-tablets]

• “Helps me out with my Achilles tendon rupture surgery . . . this has helped me actually sleep at night because it has helped so much with pain.” [From the Customer Reviews section of the Hydroxie 15mg 7-OH Tablets product webpage https://hydroxie.com/products/hydroxie-15mg-7-oh-tablets]

• “I take it for chronic pain & even on the onset of severe panic attacks.” [From the Customer Reviews section of the Hydroxie Red 15mg Tablets product webpage https://hydroxie.com/products/hydroxie-red-15mg-tablets]

• “I have MS and this makes the day easier because I’m able to get around more without pain.” [From the Customer Reviews section of the Hydroxie FREE SAMPLE product webpage https://hydroxie.com/products/hydroxie-free-sample]

Your Hydroxie 15mg 7-OH Tablets, Hydroxie Red 15mg Tablets, Hydroxie 30mg 7-OH Tablets, Hydroxie 15mg 7-OH Sublingual Strips, Hydroxie Red 15mg Sublingual Strips, Hydroxie 7-OH Shots, Hydroxie Red Shots, Hydroxie Free Sample, and Hydroxie Red Free Sample products are not generally recognized as safe and effective for the above referenced uses and, therefore, are “new drugs” under section 201(p) of the FD&C 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 FD&C Act, 21 U.S.C. 331(d) and 355(a). No approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355 is in effect for your products. Accordingly, the introduction or delivery for introduction into interstate commerce of the above products violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

Adulterated Human Food: Unsafe Food Additive

According to your product labeling, your Hydroxie 7-OH Drink Mix product, in various flavors, is a food to which 7-OH has been added.

As defined in section 201(s) of the FD&C 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.[3]

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 FD&C Act, 21 U.S.C. 348(a), and

causes the food to be adulterated under section 402(a)(2)(C)(i) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(i). The introduction or delivery for introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

There is no food additive regulation that authorizes the use of 7-OH in food. We are not aware of any information to indicate that 7-OH is the subject of a prior sanction (see 21 CFR Part 181). Furthermore, we are not aware of any basis to conclude that 7-OH 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 7-OH 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 7-OH in food meets the criteria for GRAS status. Therefore, based on our review, the use of 7-OH 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 7-OH. 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 7-OH as an added ingredient 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 7-OH for use as an ingredient in a conventional food. Therefore, 7-OH added to a conventional food is a food additive under section 201(s) of the FD&C Act and is subject to the provisions of section 409 of the FD&C Act. Under section 409, a food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. 7-OH 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 FD&C Act. Therefore, your Hydroxie 7-OH Drink Mix product, in various flavors, is adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C 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 FD&C Act.

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 FD&C Act, include your reasoning and any supporting information for our consideration.

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. Please include your firm name and the unique identifier “CMS 709661” in the subject line of the email.

Sincerely,
/s/
Jill Furman, J.D.
Director, Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

/s/
Ann M. Oxenham, J.D.
Director, Office of Compliance and Enforcement
Human Foods Program
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 You also sell some of these products in different package sizes and different strengths.

3 Under section 201(s) of the FD&C 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 FD&C 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.