

WARNING LETTER

Thang Botanicals, Inc. d/b/a 7ΩHMZ, 7-OHMZ, or 7OHMZ

MARCS-CMS 710190 — JUNE 25, 2025

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Delivery Method:

Via Email

Product:

Dietary Supplements

Feedback

Recipient:

Haywood Mitchell, Kapil Kumar
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Issuing Office:

Human Foods Program
United States

United States

WARNING LETTER

June 25, 2025

Thang Botanicals, Inc.
d/b/a 7ΩHMZ, 7-OHMZ, or 7OHMZ
Haywood Mitchell, CEO
416 Bryant Circle, Suite D
Ojai, CA 93023-4223

Registered Agents, Inc. for
Thang Botanicals, Inc.
d/b/a 7OHMZ, 7-OHMZ or 7OHMZ
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Blackbird Distribution, LLC d/b/a Indigo Distribution
Kapil Kumar, Owner
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retail@7ohmz.com
CMS # 710190

Dear Messrs. Mitchell and Kumar:

This letter concerns your dietary supplement products 7OHMZ Tropic Thunder Kratom Shot and 7OHMZ 14 mg 7-Hydroxymitragynine Tablets. Your product labeling for these products declares 7-hydroxymitragynine (7-OH)¹ as an ingredient. This letter also concerns your 7OHMZ 7-Hydroxymitragynine Gummies product (in Strawberry Acai flavor), the labeling of which states it contains 7-OH. 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

According to your product labeling, your 7OHMZ 7-Hydroxymitragynine Gummies product, in Strawberry Acai flavor, is a multi-ingredient food that contains 7-OH. Based on a review of your Strawberry Acai 7-OHMZ 7-Hydroxymitragynine Gummies label and other available information, we have concluded that the 7-OH content in this product is from the addition of either 7-OH or 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 7-OH or kratom extract in food. We are not aware of any information to indicate that 7-OH or 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 7-OH or 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 7-OH or 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 7-OH or kratom extract in food meets the criteria for GRAS status.

Therefore, based on our review, the use of 7-OH or 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 7-OH and 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 is 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 ingredient or otherwise 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 7-OH or kratom extract for use as an ingredient in a conventional food. Therefore, 7-OH and kratom extract when added to a conventional food are food additives under section 201(s) of the Act and are 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. 7-OH and kratom extract are 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 7OHMZ 7-Hydroxymitragynine Gummies product, in Strawberry Acai 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.

We note that we are concerned that your 7OHMZ 7-Hydroxymitragynine Gummies product may be appealing to children given the form of the products and the associated packaging. Although your 7OHMZ 7-Hydroxymitragynine Gummies product is labeled with the statement “Keep Out of Reach of Children,” we are concerned that this statement may not be sufficient to prevent children from consuming this product.

Adulterated Dietary Supplements

The labeling of your 7OHMZ Tropic Thunder Kratom Shot and 7OHMZ 14 mg 7-Hydroxymitragynine Tablets declares 7-OH as a dietary ingredient. Based on a review of your product labeling, the 7-OH in your 7OHMZ Tropic Thunder Kratom Shot and 7OHMZ 14 mg 7-Hydroxymitragynine Tablets 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, as noted above, 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-OCEDietarySupplements@fda.hhs.gov.

Please reference CMS #710190 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, J.D.

Director, Office of Compliance and Enforcement

Human Foods Program

Food and Drug Administration

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.

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