WARNING LETTER

7Tabz Retail, LLC

MARCS-CMS 709546 — JUNE 25, 2025

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Delivery Method:
Via Email
Product:
Drugs

Recipient:
Jonathan Daye
Zachary Daye
7Tabz Retail, LLC
5525 Johns Road
Tampa, FL 33634
United States

shop@pop7tabz.com (mailto:shop@pop7tabz.com)

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

WARNING LETTER

June 25, 2025

RE: 709546

Dear Jonathan and Zachary Daye:

This letter is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the internet address www.pop7tabz.com in May 2025 and has observed that your website offers various products marketed to contain 7-hydroxymitragynine (7-OH) including, 7Tabz 7-OH (15mg and 30mg) and 7Tabz 7-Hydroxy+Pseudo (20 mg) (hereinafter “your 7-OH products”).”[1] As described below, your 7-OH 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 observed a proliferation of products containing 7-OH and has serious concerns because 1) 7-OH products have not been evaluated by FDA for safe use and may be marketed in ways that put the public health at risk; 2) FDA has received adverse event reports involving 7-OH containing products, including your firm's products; 3) 7-OH is known to be a potent mu-opioid agonist and has been reported to have opioid-like effects in consumers; 4) FDA is concerned about the processes used to create the enhanced concentrations of 7-OH in the marketplace, as well as the potent effects produced by these doses of 7-OH; and 5) 7-OH products may be consumed by children, as some packaging and labeling may appeal to children.

Unapproved New Drugs

Based on our review of your website, www.pop7tabz.com, your 7-OH 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 that establish the intended use of your above products as drugs include, but may not be limited to, the following:

On your 7Tabz 7-OH (15mg[2] and 30mg[3]) and 7Tabz 7-Hydroxy+Pseudo 20mg[4] product webpages:
• "Pain Relief . . . Mood Boost . . . Recharge & Relax"
• "7-hydroxymitragynine (7-OH) is a small-but-mighty compound found in the Kratom plant, Mitragyna speciosa. It is considered one of the most potent alkaloids in Kratom due to its powerful affinity for binding to certain brain receptors. This makes it uniquely effective at relieving pain & enhancing mood, even in low doses."

On your 7Tabz 7-OH (15mg) product webpages[5]
• "Find your peace of mind and experience natural pain relief & relaxation. Our 7-OH tablets each contain 15mg of potent, effective 7-hydroxymitragynine extracted from organic Kratom leaf. Will leave you feeling airy, floating, and relaxed."

On your 7Tabz 7-Hydroxy+Pseudo 20mg product webpages[6] and your 7Tabz 7-OH (30mg) product webpage https://pop7tabz.com/products/30mg-4ct-7-oh-tablets:
• "Experience targeted pain relief, intense relaxation, and a feeling of pure bliss – like never before."

On your "Kratom vs 7-Hydroxymitragynine (7-OH): What's the Difference?" blog webpage https://pop7tabz.com/blogs/science/kratom-vs-7-oh:
• "How Kratom and 7-OH Work . . . [t]hese alkaloids are believed to interact with receptors that may influence mood, energy, or relaxation."

On your "FAQs" webpage https://pop7tabz.com/pages/faqs:
• "7-hydroxymitragynine (7-OH) is a small-but-mighty compound found in the Kratom plant, Mitragyna speciosa. It is considered one of the most potent alkaloids in Kratom due to its powerful affinity for binding to certain brain receptors. This makes it uniquely effective at relieving pain & enhancing mood, even in low doses."

Your 7-OH 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).

Additionally, we observed that some of your 7-OH products were previously marketed as dietary supplements on your website. Be advised, however, that dietary supplements containing 7-OH as a dietary ingredient are adulterated under section 402(f)(1)(B) of the FD&C Act, 21 U.S.C. 342(f)(1)(B), because 7-OH is 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. In fact, as noted above, available information on the use of 7-OH in products raises serious safety concerns. The introduction or delivery for introduction into interstate commerce of an adulterated dietary supplement is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

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 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 product is 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. Please include your firm name and the unique identifier “CMS 709546” in the subject line of the email.

Sincerely,
/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 You sell these products in different flavors and/or package sizes.

2 https://pop7tabz.com/products/15mg-1ct-7-oh-tablets, https://pop7tabz.com/products/15mg-4ct-7-oh-tablets, and https://pop7tabz.com/products/15mg-10ct-7-oh-tablets.

3 https://pop7tabz.com/products/30mg-4ct-7-oh-tablets

4 https://pop7tabz.com/products/20mg-1ct-7-oh-pseudo-tablets, https://pop7tabz.com/products/20mg-4ct-7-oh-pseudo-tablets, and https://pop7tabz.com/products/20mg-10ct-7-oh-pseudo-tablets

5 See webpages in footnote 2.

6 See webpages in footnote 4.