Amelyn Olson, DrPH, MPH, BSN, RN – Division Director

IMPORTANT NOTICE

Date: September 26, 2025

To: Licensed Tobacco Retailers in Sonoma County

From: Impact Sonoma Tobacco-Nicotine Prevention and Enforcement, County of

Sonoma Department of Health Services

Subject: Prohibition on the Sale of Kratom Products

Dear Retailer,

We are writing to inform you that the sale of kratom (Mitragyna speciosa) products, including 7-hydroxymitragynine (aka 7-OH), is not permitted under State and Federal law. All jurisdictions in the county share an obligation to uphold these laws and have collaborated on issuing this letter.

Impact Sonoma, a program of the Department of Health Services, regularly conducts tobacco-nicotine compliance inspections throughout the county. In this role, we have observed kratom products being sold in large quantities by many tobacco retailers. Due to health concerns and complaints received by the Department, we consulted with the California Department of Public Health (CDPH) and the Attorney General's office about these products to determine their legal status and enforcement of the prohibition of sales of these products.

While **no** businesses should be selling kratom, tobacco retailers are being contacted because kratom is commonly sold in stores that sell tobacco. Your business is receiving this letter because you have an active license to sell tobacco from the California Department of Tax and Fee Administration.

Consistent with the U.S. Food and Drug Administration (FDA), CDPH has determined that kratom is not an approved drug or dietary supplement and is considered an unsafe food additive, making its sale unlawful in California. The FDA has issued multiple warnings and enforcement actions against companies selling kratom products. In July 2025, FDA announced warning letters to firms marketing products containing concentrated 7-hydroxymitragynine, citing the serious health risks and the fact that such products are illegal to sell.

In addition, CDPH enforces laws and regulations for food and drugs in California, and California adopts federal law on food additives, dietary supplements, and new drug applications in accordance with the Federal Food, Drug, and Cosmetic. Per the FDA, kratom and its two main chemical compounds, Mitragynine and 7-hydroxymitragynine, are not approved as drugs, and kratom is not appropriate for use as a dietary supplement nor is it an approved food additive (ingredient).

Accordingly, because kratom is not approved, any such products containing kratom are adulterated per state law and thus illegal to sell to any person in California. CDPH and local health, code enforcement and law enforcement officials have the authority to take enforcement action such as embargoes, seizures, or impounds on adulterated foods. (CA HSC Sections 110555, 111860, 110150 and 108370).

CDPH's Food & Drug Branch is conducting unannounced inspections throughout CA and are expected to occur in Sonoma County.

Given these clear regulatory determinations, retailers in Sonoma County may not legally sell kratom or kratom-derived products.

It is strongly recommended that your business:

- 1. Immediately review your store's inventory for any kratom-related products.
- 2. Discontinue sale of these products and remove from the premises.
- 3. Work with your distributors to ensure **no** kratom shipments are ordered or received in the future, and to determine if any current inventory can be returned.

We ask for your cooperation in protecting our community from unsafe and illegal substances. If you have questions about this notice or need technical assistance, please contact Carley Moore at Carley.Moore@sonomacounty.gov or 707.889.8607.

Sincerely,

Terese Voge

Terese Voge, MPA

Health Program Manager

County of Sonoma Department of Health Services, Impact Sonoma Tobacco-Nicotine Prevention and Enforcement Program

Terese.Voge@sonomacounty.gov

Enclosed:

- California Department of Public Health Memorandum on Tianeptine and Kratom (April 18, 2024)
- FDA News Release: Warning Letters to Firms Marketing Products Containing 7-Hydroxymitragynine (July 15, 2025)

Cc: Director of Environmental Health, Department of Health Services, County of Sonoma

County of Sonoma, Sheriff

City of Rohnert Park, Public Safety and Code Enforcement

Town of Windsor, Police Chief and Code Enforcement

City of Santa Rosa, Police Chief and Code Enforcement

City of Petaluma, Police Chief and Code Enforcement

City of Cloverdale, Police Chief and Code Enforcement

City of Sonoma, Police Chief and Code Enforcement

City of Sebastopol, Police Chief and Code Enforcement

City of Cotati, Police Chief and Code Enforcement

FDA NEWS RELEASE

FDA Issues Warning Letters to Firms Marketing Products Containing 7-Hydroxymitragynine

Alkaloid known as 7-OH is not a lawful dietary supplement, food additive, or ingredient in any approved drug

♠ More Press Announcements (/news-events/newsroom/press-announcements)

For Immediate Release:

July 15, 2025

The U.S. Food and Drug Administration today announced seven recent warning letters sent to companies for illegally marketing products containing 7-hydroxymitragynine, also known as 7-OH. This action reflects the Agency's growing concern around novel potent opioid products being marketed to U.S. consumers and sold online and in smoke shops, gas stations, and corner stores. While 7-OH occurs naturally in trace amounts in kratom
(https://www.fda.gov/news-events/public-health-focus/fda-and-kratom), the Agency's letters focus on concentrated 7-OH products such as tablets, gummies, drink mixes, and shots, which may be dangerous.

7-OH is not lawful in dietary supplements and cannot be lawfully added to conventional foods. Additionally, there are no FDA-approved drugs containing 7-OH, and it is illegal to market any drugs containing 7-OH. Consumers who use 7-OH products are exposing themselves to products that have not been proven safe or effective for any use.

The warning letters address the illegal marketing of <u>products containing 7-OH</u>
(https://www.flickr.com/photos/fdaphotos/albums/72177720327395989)
(https://www.fda.gov/about-fda/website-policies/website-disclaimer). These letters specifically focus on products containing 7-OH as an added ingredient or enhanced levels of 7-OH. Some products are adulterated conventional foods or dietary supplements because 7-OH does not meet the relevant safety standard. Others are unapproved new drugs with unproven claims such as relieving pain and managing anxiety.

The FDA issued warning letters to:

- <u>Shaman Botanicals, LLC (http://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/shaman-botanicals-llc-709622-06252025)</u>
- <u>My Smoke Wholesale (http://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/my-smoke-wholesale-710314-06252025)</u>
- Relax Relief Rejuvenate Trading, LLC dba RRR Trading or EDP Kratom
 (http://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/relax-relief-rejuvenate-trading-llc-dba-rrr-trading-or-edp-kratom-709475-06252025)
- Thang Botanicals, Inc. dba 7ΩHMZ, 7-OHMZ, or 7OHMZ (http://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/thang-botanicals-inc-dba-7ohmz-7-ohmz-710190-06252025)
- Royal Diamond Imports, Inc. dba Roxytabs.com (http://www.fda.gov/inspectionscompliance-enforcement-and-criminal-investigations/warning-letters/royal-diamondimports-inc-709540-06252025)
- <u>Hydroxie, LLC (http://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hydroxie-llc-709661-06252025)</u>
- <u>7Tabz Retail, LLC (http://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/7tabz-retail-llc-709546-06252025)</u>

The letters requested that the recipients respond within 15 business days.

Media:

HHS Request for Comment (https://www.hhs.gov/request-for-comment-form/index.html? Agency=ASPA)
202-690-6343

Consumer:

888-INFO-FDA

1 Also known as 7-OH-mitragynine, 7-OHMG, and 7-HMG

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California Department of Public Health

MEMORANDUM

TO: Local Health Jurisdictions

FROM: California Department of Public Health (CDPH): Food and Drug

Branch (FDB), Substance Abuse Prevention Branch (SAPB)

DATE: April 18, 2024

SUBJECT: Tianeptine and Kratom

This fact sheet is provided for Local Health Jurisdictions who requested FDB and SAPB to provide information about <u>tianeptine</u>, also referred to as "Gas-Station Heroin," and <u>kratom</u>.

About Tianeptine

- Tianeptine, also known as "Gas-Station Heroin," is not approved by the US Food and Drug Administration (FDA) for any medical use.
- It's illegally sold online and in stores with claims to treat various conditions like anxiety, depression, and pain.
- While other countries approve it for depression and anxiety, they also warn about its addiction potential.
- Since 2018 the FDA has issued multiple <u>advisories</u> and <u>warnings</u> to consumers about products with tianeptine, including it being linked to serious harm, overdoses, and death.

About Kratom

- Kratom, like tianeptine, lacks FDA approval for medical use.
- Derived from a tropical tree, it's sold illegally online and in stores with claims to treat pain, anxiety, and opioid withdrawal.
- The FDA has <u>seized</u> kratom products due to <u>safety concerns</u>.
- An estimated 1.7 million Americans aged 12 and older used kratom in 2021, according to the Substance Abuse and Mental Health Services Administration's <u>National Survey on Drug Use and Health</u>.

Are they drugs or supplements?

- Neither tianeptine nor kratom is approved as drugs or supplements.
- The FDA considers them unsafe food additives, making their sale illegal in the US.

CDPH's role related to supplements or products like Tianeptine and/or Kratom

 The California Department of Public Health (CDPH) oversees food, drug, and medical device safety. Fact sheet memo re tianeptine and kratom Page 2 April 18, 2024

 CDPH investigates complaints about products like tianeptine and kratom and shares findings with relevant authorities, including local health jurisdictions (LHJs).

What Can Local Health Jurisdictions Do?

- Local environmental health agencies (LEHAs) can request stores to voluntary remove products containing tianeptine or kratom and/or LEHAs can impound such products.
- LEHAs can also provide educational materials about the risks of these substances.

Clinician Awareness

- Tianeptine and kratom can lead to dependence, addiction, and overdose.
- Overdose can be treated with opioid reversal medication like naloxone.
- Withdrawal symptoms are similar to opioids and may be treated with medications like buprenorphine and naloxone.