

United States Senate

WASHINGTON, DC 20510

October 7, 2026

The Honorable Terrance Cole
Administrator
U.S. Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA 22202

Kyle Diamantas
Acting Commissioner of the Food and Drug Administration
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Administrator Cole and Acting Commissioner Diamantas:

We welcome the Drug Enforcement Administration's (DEA) effort to initiate the federal regulation of 7-hydroxy mitragynine (7-OH) following the Food and Drug Administration's scheduling recommendation.¹ We also applaud DEA's recent emergency scheduling of 7-OH mitragynine-related substances.² That said, we encourage DEA, in consultation with the Food and Drug Administration (FDA), to consider scheduling the entire kratom plant, including all levels of 7-OH (not simply the threshold limit as stated in the Notice of Intent) and all other pharmacologically active alkaloids present in the plant. It is imperative that the final emergency scheduling order for 7-OH be expeditiously promulgated.

As supporters of the Halt All Lethal Trafficking of Fentanyl Act (HALT Fentanyl Act), we are alarmed to see that an opioid known to be approximately 14 times more potent than morphine (when given orally) is currently not only legal, but entirely unregulated.³ Even more concerning is that kratom-derived concentrates, other alkaloids, and semi-synthetic analogues like mitragynine pseudoindoxyl, MGM-15, and MGM-16 are making kratom-labeled products more dangerous than 7-OH with an increased abuse liability.⁴ These semi-synthetic substances may be found in kratom-labeled products unbeknownst to the user. As stated in DEA's recent emergency scheduling order, these semi-synthetic analogues are pharmacologically similar to and more potent than, schedule II opioids like morphine.⁵ Permanently placing all levels of these synthetic compounds into Schedule I of the Controlled Substances Act is an essential and necessary action to ensure the safety of kratom consumers and to keep products with compounds even more dangerous than 7-OH from widespread availability.

¹ *Schedules of Controlled Substance: Temporary Placement of 7-Hydroxymitragynine above a Specified Threshold in Schedule I*, 91 Fed. Reg. 40917 (proposed July 6, 2026) (to be codified at 21 C.F.R. pt. 1308).

² 21 C.F.R. § 1308.11(h)(ii)(89-91) (2026).

³ Kenjiro Matsumoto et al., *Orally Active Opioid μ/δ Dual Agonist MGM-16, a Derivative of the Indole Alkaloid Mitragynine, Exhibits Potent Antiallodynic Effect on Neuropathic Pain in Mice*, 348 THE J. OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS 383, 387 (2014).

⁴ See *id.* at 386.

⁵ *Schedules of Controlled Substances: Temporary Placement of Mitragynine Pseudoindoxyl, MGM-15, and MGM-16 in Schedule I*, 91 Fed. Reg. 40909 (proposed July 6, 2026) (to be codified at 21 C.F.R. pt. 1308).

The science clearly demonstrates the abuse liability, potential for abuse, and threat to public health and safety presented by these opioids. However, even after the final publication of the temporary order scheduling 7-OH, 7-OH less than 0.05% (weight/weight, weight/volume, or volume/volume) or less than 1 mg (in the article) will remain easily accessible to the American public. In the United States, there are no FDA-approved kratom drug products or over-the-counter pharmaceuticals containing kratom that are legally sold in pharmacies. The FDA continues to warn consumers not to use kratom because of the risk of serious adverse health effects including liver toxicity, seizures, and substance abuse disorder.⁶ Furthermore and unsurprisingly, data from the National Drug Early Warning System (NDEWS), which monitors emerging drug trends in real-time to inform public health and safety responses, has also sounded the alarm on kratom.

According to NDEWS, from January 1, 2023, to April 30, 2026, 3,672 suspected nonfatal overdose encounters with emergency medical services involving 7-OH mitragynine, mitragynine, or kratom use were recorded across 38 states.⁷ From a regional perspective, 736 encounters occurred in Western states, 526 in the Midwest, 2,007 in Southern states, and 403 in Northeastern states.⁸ According to the National Poison Data System (NPDS), between 2015 and 2025, poison control centers received 14,449 kratom exposure reports.⁹ During this time, 3,434 reports were submitted in 2025, which is currently the record high, representing an increase of approximately 1,200% compared with reports submitted in 2015.¹⁰ Similarly, the Iowa Poison Control Center stated that in 2023 and 2024 there were 24 reported kratom exposure calls, and 53 such calls in 2025, accounting for an increase in kratom-related exposures in Iowa of approximately 120%.¹¹

We frequently hear from constituents and concerned parents who have lost loved ones, and recovering users who warn us constantly about the addictive nature of kratom and its analogues. We worry the availability of these products is providing consumers with a false sense of security because they are readily available and marketed as “natural.”

We urge DEA, in consultation with FDA, to initiate proceedings to permanently schedule all harmful substances found in kratom, including 7-OH, MGM-15, MGM-16, and mitragynine pseudoindoxyl.

Furthermore, we urge the Food and Drug Administration to conduct the necessary scientific and medical evaluations of these substances and provide a permanent scheduling recommendation to the Drug Enforcement Administration for the full kratom plant, its derivatives, and all levels of the semi-synthetic analogues like mitragynine pseudoindoxyl, MGM-15, and MGM-16 that are being marketed as natural products.

⁶ *FDA and Kratom*. (Dec. 12, 2025), <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>.

⁷ *Top 10 US Counties per Region with the Highest Rates of EMS Encounters Involving Nonfatal 7-OH, Mitragynine, or Kratom Use per 10,000 Population January 1, 2023 - April 30, 2026*, NAT'L DRUG EARLY WARNING SYS. 1, 1 (May 15, 2026), https://ndews.org/wordpress/files/2026/05/05.15.26_NDEWS-2026-7oh.pdf.

⁸ *Id.* at 2.

⁹ Eleanor Blair Towers et al., *Increases in Kratom-Related Reports to Poison Centers — National Poison Data System, United States, 2015–2025*, 75 MORBIDITY & MORTALITY WKLY. REP. 139, 139 (2026).

¹⁰ *Id.*

¹¹ *Iowa Drug Control Strategy and Drug Use Profile*. IOWA DEP'T OF PUB. SAFETY OFF. OF DRUG CONTROL POL'Y, 33 (2026), <https://dps.iowa.gov/media/3134/download?inline>.

Please reply in writing no later than October 15, 2026.

Sincerely,



Charles E. Grassley
United States Senator



Michael S. Lee
United States Senator



Susan M. Collins
United States Senator

cc:

The Honorable Russell Vought
Director
Office of Management and Budget
725 17th Street, NW
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