United States Senate

WASHINGTON, DC 20510

November 16, 2026

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

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

Dear Administrator Cole and Acting Commissioner Diamantas:

Kratom is an opioid. Interested parties' word play often involves differentiating between "natural" and "synthetic" products. Surely artificially enhanced Kratom products are often more dangerous, but that does not mean that so-called "natural" ones are safe. Nor does marketing a product as "natural" make it a dietary supplement or recognized as safe. No health authority to date has said as much.

Our expectation is that policy decisions made on behalf of the American people treat their safety as the priority. To that end, we are requesting from the Food and Drug Administration (FDA) the evaluations supporting the revised 7-OH threshold limit and a letter justifying the revised, higher threshold. We also urge the Drug Enforcement Administration (DEA) to revert to the initial July 2026 order 7-OH threshold and place mitragynine pseudoindoxyl in schedule I.

On July 6, 2026, following a recommendation from the Department of Health and Human Services (HHS), DEA published a Notice of Intent (NOI) to place 7-hydroxymitragynine (7-OH) in schedule I of the CSA above the threshold level of 0.05%.[1] On the same day, DEA published a second NOI proposing the placement of three semi-synthetic, kratom-related products (MGM-15, MGM-16, and mitragynine pseudoindoxyl) in schedule I of the CSA. Then on August 26, 2026, DEA published the temporary order officially regulating the semi-synthetic, kratom-related products and placed them in schedule I of the CSA.[2] Remarkably, DEA then withdrew these actions, ultimately setting a **more permissive** 7-OH limit.[3] Additionally, DEA published a new temporary scheduling order removing the semi-synthetic and highly potent opioid, mitragynine pseudoindoxyl (MP), allowing its presence in so-called "natural" Kratom products below a threshold limit.[4]

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[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).
[2] 21 C.F.R. § 1308.11(h)(ii)(89-91) (2026).
[3] *Schedules of Controlled Substances: Temporary Placement of 7-Hydroxymitragynine and Mitragynine Pseudoindoxyl Above a Specified Threshold in Schedule I*, 91 Fed. Reg. 65,370 (Oct. 14, 2026) (proposed rule).
[4] *See id.*

Kratom is a drug in any form with addictive properties, and we believe this combined threshold level for 7-OH and MP set by DEA is inappropriately high and unsound. MP is a semi-synthetic opioid that is more potent than morphine. To date whether MP is naturally occurring in the plant is unclear. If the Administration's goal is to remove all unsafe products from the shelves, particularly synthetic or enhanced kratom products, this order misses the mark.

We are not alone in our view that all Kratom is unsafe. This position is shared by physicians trained in addiction treatment and public health experts.[5] The FDA states that they will "... continue to warn the public against the use of kratom for medical treatment because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder."[6] The psychoactive alkaloids of the kratom plant are potentially dangerous substances that should be treated with caution, particularly given the lack of adequate regulation on its products.

To say anything else would be a disservice to the public particularly those who are recovering from drug dependence, those seeking "natural" alternatives to pain management, and our most vulnerable young people. We have long advocated for expanding access to treatments for those in opioid-dependence recovery with treatments that have proven to be safe. While we are concerned about the dangers of kratom in all forms, the new rules issued by DEA could leave synthetic and especially dangerous products on shelves. The American people deserve peace of mind about what is sold on marketplace shelves and a public health system that makes sound regulatory decisions.

Therefore, our question is simple; if the Administration's goal is to protect the health and safety of all Americans, why do your new actions permit concentrations of 7-OH and MP that are higher than what occurs naturally in the kratom plant? In fact, the new scheduling orders double the previously allowable limit for 7-OH, raising it from 0.05% to 0.1% and de-schedules MP, allowing it to remain in Kratom products sold in America.

The new action setting a combined threshold for 7-OH and MP does not successfully or safely accomplish the goal of limiting this unregulated market to "natural" Kratom products. Under the new rule, synthetic products with concentrations of MP (an opioid more potent than 7-OH[7]) of up to 0.1% would remain legal. That is not "natural" kratom; even if we were to assume that MP occurs naturally in the kratom plant (which the science is divided on at best), it is almost certainly not at these levels. It is our belief that substances which FDA's own scientific review (according to HHS Secretary Kennedy in his published remarks) indicates are approximately two to nine times more potent than morphine do not belong in unregulated products available to consumers.[8]

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[5] *See* Kolodny, Andrew & Christopher P. Holstege, *Kratom Is an Opioid*, 46 J. Clinical Psychopharmacology (forthcoming 2026) (published online Oct. 15, 2026), https://doi.org/10.1097/JCP.0000000000002272.

[6] U.S. Food & Drug Admin., *FDA and Kratom*, https://www.fda.gov/news-events/public-health-focus/fda-and-kratom.

[7] Kamble et al., *Metabolism of a Kratom Alkaloid Metabolite in Human Plasma Increases Its Opioid Potency and Efficacy*, 3 ACS Pharmacology & Translational Science 1063, 1063–68 (2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7737207/.

[8] U.S. Dep't of Health & Hum. Servs., *HHS Recommends Science-Based Thresholds to Target Dangerous Enhanced Kratom Products* (Oct. 9, 2026), https://www.hhs.gov/press-room/hhs-recommends-thresholds-enhanced-kratom-products-7-oh-mgpi.html.

- We request that FDA provide us the scientific and medical evaluations they collected to arrive at the higher threshold limit for 7-OH (1mg/g for solids or 1mg/mL for liquids) with an explanation why this new limit better protects the public when compared to the previous scheduling order for 7-OH which contained a lower threshold.
- We also request that DEA, in consultation with FDA, reconsider their higher, newly determined threshold level for 7-OH and revert to the previous order which placed mitragynine pseudoindoxyl in schedule I of the CSA. Please provide an explanation if DEA decides not to revert to the previous order.

We look forward to your reply no later than November 30, 2026.

Sincerely,

Charles E. Grassley
United States Senator

Susan M. Collins
United States Senator

Rick Scott
United States Senator

Mike Crapo
United States Senator

Bill Cassidy, M.D.
United States Senator

Jerry Moran
United States Senator

Shelley Moore Capito
United States Senator

James E. Risch
United States Senator