



March 18, 2026

The Honorable Martin A. Makary, M.D., M.P.H.  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Commissioner Makary:

We appreciate the Food and Drug Administration's (FDA) targeting 7-hydroxymitragynine (7-OH), a concentrated byproduct of the kratom plant. As you know, 7-OH is an opioid that can be more potent than morphine. We are particularly concerned with the products that appeal to teenagers and children. Kratom-derived concentrates in forms like tablets, gummies, and drink mixes are available online and in gas stations. This makes them easily accessible and attractive to young Americans.

Recommending scheduling action of 7-OH under the Controlled Substances Act (CSA) is an important first step. However, we encourage you to consider scheduling the whole kratom leaf, given that some of the most accessible and addictive products contain whole kratom leaf, not 7-OH.

So-called "herbal supplements" are sold at many gas stations and retailers across the country. Their ingredients include kava extract, which the company says promotes relaxation and lifts mood. They also include kratom leaf, which is said to enhance energy and focus. The supplement only contains trace amounts of 7-OH, so it would not be regulated under the CSA if 7-OH is scheduled.<sup>1</sup>

To be clear, the kratom leaf acts on mu-opioid receptors, similar to opioids.<sup>2</sup> Frequent use leads to tolerance, dependence and withdrawal symptoms that resemble those from morphine or heroin. Reported side effects of kratom include nausea, vomiting, constipation, tremors, seizures, hallucinations, elevated blood pressure and liver damage.<sup>3</sup>

Young people across the country have reported growing addicted to kratom supplements, consuming up to a dozen products a day and going through severe withdrawal symptoms after

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<sup>1</sup> <https://www.reuters.com/press-releases/botanic-tonics-feel-free-applauds-florida-ban-synthetic-7-oh-2025-08-13/>

<sup>2</sup> Smith, K. E., Grundmann, O., Swogger, M. T., & Garcia-Romeu, A. (2023). Kratom (*Mitragyna speciosa*): Pharmacology and use of a naturally occurring atypical opioid. In *The Oxford Handbook of Opioids and Opioid Use Disorder* (pp. 386-418). Oxford University Press. <https://doi.org/10.1093/oxfordhb/9780197618431.013.15>

<sup>3</sup> <https://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/in-depth/kratom/art-20402171>

ceasing use.<sup>4</sup> Some cities, counties and states have responded by banning kratom or raising the minimum purchase age to 18 or 21. But in many areas, enforcement remains inconsistent, and some addiction specialists say clearer federal guidance is needed.

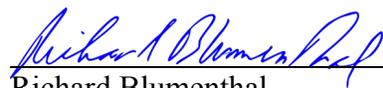
Singling out 7-OH to schedule would leave these addictive products on the shelf and tacitly declare them safe for consumption. There will be no standardized control over product quality, concentration, or labeling, allowing inconsistent and potentially dangerous products to stay on the market.

We remain committed to protecting America's youth from dangerous and addictive substances and look forward to working with you to address the full scope of the rising danger of the kratom plant through the CSA.

Sincerely,



Pete Ricketts  
United States Senator



Richard Blumenthal  
United States Senator



Jeanne Shaheen  
United States Senator



Mike Crapo  
United States Senator



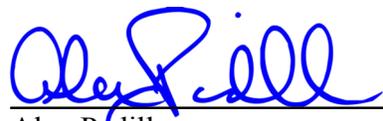
Marsha Blackburn  
United States Senator



Steve Daines  
United States Senator



James C. Justice  
United States Senator



Alex Padilla  
United States Senator

<sup>4</sup> <https://www.cnn.com/2025/08/26/health/feel-free-drink-kratom-kava-addictive-wellness>



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