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U.S. Moves to Restrict Potent Kratom Ingredient Amid Rising Health Concerns

July 29, 2025

— Categories: Breaking News

U.S. health authorities are pushing for tighter regulation on a powerful chemical derived from kratom, a herbal substance commonly found in convenience store supplements, citing growing risks to public health and calls from industry leaders for clearer oversight.

The U.S. Food and Drug Administration (FDA) is recommending a federal ban on 7-hydroxymitragynine (7-OH), a highly concentrated and potentially dangerous component of kratom, a tropical plant native to Southeast Asia. While kratom itself has been promoted as a natural remedy for pain, anxiety, and opioid withdrawal, 7-OH is a chemically enhanced compound with potency likened to morphine. Officials warn that its increasing presence in

over-the-counter energy drinks, gummies, and powders often sold without proper evaluation poses serious risks to consumers.

The U.S. Department of Health and Human Services (HHS) clarified in a recent statement that the crackdown is focused solely on the synthetic 7-OH, not on traditional kratom leaf products. According to FDA Commissioner Marty Makary, "7-OH is an opioid that can be more potent than morphine. We need regulation and public education to prevent another wave of the opioid epidemic."

The FDA's proposal seeks to classify 7-OH under Schedule I of the Controlled Substances Act, a list reserved for the most dangerous drugs with no accepted medical use, such as heroin and LSD. This recommendation now awaits review by the Drug Enforcement Administration (DEA), which enforces federal drug policy.

The supplement industry has not opposed the move. Several companies have welcomed it. Ryan Niddel, CEO of Utah-based supplement firm Diversified Botanics, praised the FDA's efforts: "The agency demonstrated the exact kind of data-driven, proactive regulatory excellence needed to safeguard unwitting consumers across the U.S."

This shift comes after years of FDA scrutiny and pushback from kratom advocates. In 2016, the DEA attempted to place kratom itself under Schedule I, but a flood of public objections, including bipartisan letters from over 60 members of Congress, halted the process. Since then, the FDA has investigated the plant more thoroughly, concluding in 2018 that its compounds mirror the effects of opioids, an addictive drug class responsible for thousands of deaths annually in the U.S.

Most recently, the FDA issued warning letters to seven manufacturers selling kratom-laced drinks and gummies. These products, the agency noted, violated FDA rules by promoting unverified health claims, including treatment for arthritis, pain, and anxiety.

While organizations like the American Kratom Association (AKA) continue to advocate for kratom to be regulated as a dietary supplement rather than a controlled substance, health officials remain firm in their stance on 7-OH. Their goal: prevent the misuse of synthetic or overly concentrated kratom compounds that are marketed with little oversight and may be fueling new forms of substance abuse.

In parallel with the kratom review, the FDA has also cautioned against other unapproved substances, including tianeptine, an antidepressant sold in similar packaging and dubbed by some as “gas station heroin.” Though banned in several states, these substances remain unregulated at the federal level.

As the regulatory process unfolds, the spotlight remains on balancing public safety with access to natural remedies. For now, the message from federal health officials is clear: when it comes to chemically altered compounds like 7-OH, the risks outweigh the benefits.