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DEA Taking Steps to Issue Temporary Scheduling Order for Kratom-Based Products Including High Levels of 7-OH and 7-OH-Related Synthetic Components

On July 1, the U.S. Drug Enforcement Administration (DEA) filed two Federal Register notices that together signaled its intent to temporarily place several synthetic alkaloids associated with *Mitragyna speciosa* (commonly known as kratom leaf or kratom), including 7-hydroxymitagynine (7-OH) and three related substances (mitragynine pseudoindoxyl, MGM-15, and MGM-16) into Schedule I of the Controlled Substances Act (CSA). According to the DEA, two naturally occurring psychoactive alkaloids in kratom, mitragynine, and 7-OH, have led to the "proliferation" of products containing drugs synthesized from mitragynine (mitragynine pseudoindoxyl, which is a chemical rearrangement product of 7-OH) and MGM-15 (a synthetic derivative of 7-OH) that have opioid-like effects. While not commercially marketed yet, MGM-16, the 9-fluoro derivative of mitragynine pseudoindoxyl, is also a product that has a highly potent opioid effect.

According to the notices, U.S. Department of Health and Human Services (HHS) and the U.S. Federal Food and Drug Administration (FDA) have confirmed that these kratom-related synthetic substances have no accepted medical use and a high potential for abuse. After the 30-day comment period for the notices, the Office of the Assistant Secretary for Health will provide comments submitted to the public docket to the Attorney General for consideration. Once the comments have been considered, the Attorney General may then issue a temporary scheduling order placing 7-OH above a certain threshold in Schedule I. The CSA provides the Attorney General with the authority to issue a temporary scheduling order placing a substance in Schedule I of the CSA for two years, if such action is necessary to avoid

an imminent hazard to public safety.

In particular, the DEA's and HHS's press release noted that scheduling is warranted given the "proliferation" of commercial products containing extra amounts of 7-OH or semi-synthetic 7-OH. The DEA observed that these products are marketed online and sold in gas stations, convenience stores, and smoke shops in formulations including powders, tablets, capsules, gummies, and dissolvable strips. DEA's laboratory tests determined that these commercial synthetic kratom products contain higher amounts of 7-OH than what is found in natural-occurring, botanical kratom at levels from . DEA's notices are part of a broader effort to combat the drug abuse epidemic, especially concerning dangerous synthetic products.

DEA Administrator Terrance Cole said on the same day as the notices went out: "Today's action targets highly concentrated, synthetic 7-OH products, which pose a growing threat to public safety and health. Temporarily scheduling these substances underscores the emphasis this Administration has put on the safety, health and well-being of the American people." "This action gives law enforcement and public health partners the tools needed to address this emerging threat. We appreciate the FDA's scientific expertise and our continued partnership with HHS to address emerging threats, and we will continue to act aggressively when dangerous substances threaten Americans."

DEA's notice of intent aligns with HHS's priorities. "I commend the DEA for taking decisive action to address these addictive and harmful substances," said HHS Secretary Robert F. Kennedy, Jr. "7-OH, MP, MGM-15, and MGM-16 are dangerous opioids that fuel addiction and put American lives at risk. HHS reviewed the science and recommended this action.

The official notices published in the Federal Register on July 6, including 7-OH (here) and three related substances (here). Once the temporary scheduling orders take effect, the manufacture, distribution, sale, and possession of the covered 7-OH and related substances will become subject to criminal, civil, and administrative provisions of the Controlled Substances Act.

Key Takeaways

DEA's proposed temporary scheduling of synthetic 7-OH and related psychoactive substances should not affect botanical kratom products that contain naturally occurring mitragynine and 7-OH. Instead, the DEA is targeting scheduling products that contain higher than naturally occurring 7-OH or mitragynine or synthetic 7-OH related substances with psychoactive opioid-like effects and higher risks. DEA, in conjunction with HHS and FDA, has determined that its proposed temporary scheduling order will address an imminent threat of products with these substances at proposed threshold levels to protect public safety given their effects are highly unpredictable. As early August 5, 2026, companies should be on the lookout for the Attorney General to potentially issue a temporary Schedule I order to last two years and ultimately longer for enhanced kratom products with higher amounts of 7-OH and mitragynine or the synthetic 7-OH related substances. We will continue to monitor comments on the published notices and comments, as well as the Attorney General's actions to provide an update.

This blog was drafted by Brian Malkin, Co-Chair of the Spencer Fane Cannabis and FDA Pharmaceutical and Biologics Market Teams. For more information, visit spencerfane.com.

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