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DEA Temporarily Schedules Synthetic Kratom-Related Products Mitragynine Pseudoindoxyl MGM-15 and MGM-16 in Schedule I – Is 7-OH Next?

On August 25, 2026, the Drug Enforcement Administration (DEA) issued a temporary order scheduling three synthetic kratom-related products derived from naturally occurring 7-hydroxymitragrynine (7-OH): mitragynine pseudoindoxyl, MGM-15, and MGM-16 in Schedule I of the Controlled Substances Act (CSA). The scheduling order applies to isomers, esters, ethers, and salts of these substances and imposes regulatory controls and administrative, civil, and criminal sanctions for people who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analyses with, or possess), or propose to handle these substances.

The scheduling follows the DEA's July 1 intent to schedule these products, as well as products containing certain threshold amounts of 7-OH in the article, which we reported on here. All of these substances are associated with *Mitragyna speciosa* (commonly known as kratom), but of these only 7-OH is naturally occurring in small amounts. Mitragynine pseudoindoxyl is a chemical rearrangement product of 7-OH, MGM-15 is a synthetic derivative of 7-OH, and MGM-16 is the 9-fluoro derivative of mitragynine pseudoindoxyl.

Following a 30-day comment period for the two notices, the Office of the Assistant Secretary for Health (ASH) of the U.S. Department of Health and Human Services (HHS) provided comments submitted to the public docket to the Attorney General (AG) for consideration. The AG has the authority to temporarily schedule these substances in Schedule I for two years if deemed necessary to avoid an imminent hazard to public safety, which may be extended for up to a year, if the substances are not scheduled in another category or there is an exemption or approval under

the Federal Food, Drug and Cosmetic Act. The AG in turn has delegated the scheduling authority to the DEA Administrator. Prior to the notices, the ASH confirmed there were no investigational drug applications (INDs) or approved new drug applications (NDAs) for these three substances and that HHS had no objections to the temporary placement of these substances in Schedule I of the CSA.

The DEA Administrator is charged with considering three of the eight factors set forth in 21 U.S.C. § 811(c) for drug scheduling: the substances' history and current pattern of abuse, the scope, duration, and significance of abuse, and what, if any, risk there is to the public health. Schedule I drugs have a high potential for abuse, no currently accepted medical use in treatment in the U.S., and a lack of accepted safety for use under medical supervision. First, DEA noted that there has been a shift from natural leaf kratom products to flavored, standardized, and high-potency semisynthetic substances like mitragynine pseudoindoxyl, MGM-15, and MGM-16. These substances exhibit a strong affinity for the mu-opioid receptor (MOR) and function as MOR agonists with health risks similar to morphine and fentanyl, including physical and psychological dependence, and respiratory depression. Next, DEA found the scope, duration, and significance of abuse was significant due to the substances' high opioid potency and commercial availability with deceptive advertising misleading consumers to think the effects would be similar to kratom or that they could be used to ease stress and tension, provide internal calm or reduced restlessness, or provide mental clarity. DEA said the products had a rapid onset with a duration of effect that lasted several hours with the potential for toxicity and a low barrier to entry with use of fruity flavors or chewable formats, and a prevalence of use at approximately two million by 2022. Finally, the risk to the public health was consistent with other Schedule I products and substantial – preclinical data demonstrated mitragynine pseudoindoxyl was about 100 times more potent than mitragynine, and MGM-15 and MGM-16 are about 50 to 240 times more potent than morphine with signs of opioid physical dependence in animal models. The products' ready availability in retail establishments with no age restriction poses additional risk. The uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession and abuse of these three substances posed an imminent risk to public safety.

Key Takeaways

Beginning on August 25, researchers will need Schedule I licenses to continue working with these three substances. Retail sales of the substances to the general public in any quantity are not allowed under the CSA. Any individual who does not obtain a Schedule I registration cannot handle the three substances and must surrender all currently held quantities, and for those with Schedule I registrations, appropriate security must be maintained. Any commercial sale consistent with schedule I must maintain adequate records and controls. The DEA does not believe this temporary scheduling requires notice-and-comment under the Administrative Procedure Act or that it is a "rule."

Next Steps

DEA's actions do not affect botanical kratom products containing naturally occurring mitragynine and 7-OH. Instead, they target synthetic 7-OH-related substances with opioid-like psychoactive effects and greater risks. Starting on August 25, and for at least the next two years, retailers will need to cease consumer sales of products containing mitragynine pseudoindoxyl, MGM-15, or MGM-16, and appropriate Schedule I registrations will be required for researchers or other non-public handlers of these substances to avoid regulatory actions. We will continue to monitor how DEA's temporary scheduling is implemented and enforced, as well as any ancillary state scheduling actions.

This blog was drafted by Brian Malkin, co-lead of the Spencer Fane FDA Pharmaceutical and Biologics Market Team. For more information, visit spencerfane.com.

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