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Legal Sidebar

Temporary Control of 7-Hydroxymitragynine (7-OH) and Other Kratom-Related Substances Under the Controlled Substances Act

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On July 1, 2026, the U.S. Drug Enforcement Administration (DEA) announced its intent to temporarily place in Schedule I of the Controlled Substances Act (CSA) a chemical found in the kratom plant, 7-hydroxymitragynine (7-OH), and three related substances known as mitragynine pseudoindoxyl (MP), dihydro-7-hydroxymitragynine (MGM-15), and 9-fluoro-dihydro-7-hydroxymitragynine (MGM-16). The planned temporary scheduling was not to apply to the kratom plant itself or other derivatives of the plant, as long as they contain concentrations of 7-OH that fall below specified thresholds. The temporary scheduling of MP, MGM-15, and MGM-16 took effect on August 26, 2026. The same day, DEA extended the comment period on the proposed temporary scheduling of 7-OH. On October 14, 2026, DEA published two new notices in the *Federal Register*. One announced DEA's intent to adopt a revised threshold approach for the temporary scheduling of 7-OH and MP, while the other stated DEA's intent to temporarily schedule MGM-15 and MGM-16 as previously announced.

This Legal Sidebar provides an overview of the proposed temporary scheduling of 7-OH and the temporary scheduling of MP, MGM-15, and MGM-16. After outlining the CSA's scheduling regime and providing background on the kratom plant and its derivatives, it summarizes the July 2026 and October 2026 temporary scheduling notices and the August 2026 scheduling order and discusses the legal effects of temporary scheduling. The Sidebar closes with considerations for Congress related to the regulation of kratom, 7-OH, MP, MGM-15, and MGM-16.

CSA Legal Framework

The CSA regulates drugs and other substances—whether medical or recreational, legal or illicit—that pose a risk of abuse and dependence. DEA, an agency within the Department of Justice, is the federal agency primarily responsible for implementing and enforcing the CSA.

Substances become subject to the CSA through placement in one of five lists, known as Schedules I through V. Controlled substances in Schedule I are subject to the most stringent controls, as they are deemed to have a high potential for abuse and no currently accepted medical use. It is legal to produce,

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dispense, and possess Schedule I substances only in the context of federally approved scientific studies. Substances in Schedules II through V have accepted medical uses and have been deemed to pose progressively lower risks of abuse and dependence. Those substances may be used for medical purposes, generally by prescription. Anyone who handles a controlled substance, other than an ultimate user, must register with DEA and comply with CSA registration requirements, which include security and reporting obligations. Unauthorized activities involving controlled substances are criminal offenses that can carry significant fines and imprisonment.

Either Congress or the DEA Administrator can place a substance in a CSA schedule, move a substance to a different schedule, or remove a substance from the schedules. Congress can take those scheduling actions by enacting legislation. DEA, for its part, may make permanent scheduling decisions through a formal rulemaking process. The agency can also temporarily place substances in Schedule I on an emergency basis when "necessary to avoid an imminent hazard to the public safety." The CSA does not authorize DEA to use this temporary scheduling authority to place a substance in Schedules II-V. DEA must notify the Secretary of Health and Human Services (HHS) and publish notice of its intent to temporarily schedule a substance in the *Federal Register* at least 30 days before implementing such scheduling, but is not required to follow the administrative rulemaking process for permanent scheduling. An initial temporary scheduling order may be effective for up to two years. If DEA undertakes permanent administrative scheduling of a substance, it may extend the temporary scheduling for up to one year while permanent scheduling proceedings are pending. Unlike permanent administrative scheduling, temporary scheduling is not subject to judicial review.

Kratom and Its Derivatives

Kratom, scientific name *Mitragyna speciosa*, is an evergreen tree related to the coffee plant that is native to parts of Southeast Asia. People living in the plant's native range have traditionally consumed the leaves of the tree for medicinal and religious purposes. The effects of kratom depend on the dosage consumed. At low doses, it has a stimulant effect, while at higher doses it acts as a sedative.

According to the National Institute on Drug Abuse (NIDA), the most well-studied compounds in kratom are 7-OH and mitragynine. DEA has determined that the kratom plant contains only trace amounts of 7-OH, but 7-OH can be synthesized from mitragynine, which is present in the plant in larger quantities. Both compounds activate mu-opioid receptors, meaning they physically affect the brain in the same way as opioids, but NIDA states that "the resulting effects only partially compare to those of opioids like heroin or oxycodone." According to NIDA, kratom leaves and mitragynine have not been found to cause the respiratory depression (i.e., slow and shallow breathing) associated with a life-threatening opioid overdose, while 7-OH has been found to cause respiratory depression that can be reversed by naloxone.

Products containing kratom and 7-OH are widely sold in gas stations and smoke shops and online in various forms including powders, tablets, gummies, and sublingual films, and are sometimes colloquially called "gas station heroin." Some have raised health and safety concerns about the use of kratom and 7-OH, while others warn that consumer kratom products may contain dangerous contaminants. At the same time, some point to potential medical uses of kratom, including in the treatment of opioid use disorder, though more study would be required to determine whether kratom or its derivatives are safe and effective for medical use.

Temporary Scheduling of Kratom-Related Substances

Federal and state regulators have been considering whether and how to regulate kratom for years. In 2016, DEA issued notice of its intent to temporarily place mitragynine and 7-OH in Schedule I on an emergency basis. However, after receiving numerous comments from stakeholders, DEA withdrew that notice and did not control the two compounds. DEA has listed kratom as a Drug and Chemical of Concern, which

does not impose legal restrictions on the substance under the CSA. In addition, the Food and Drug Administration (FDA) has taken the position that kratom is an unapproved new dietary ingredient and an unsafe food additive and therefore may not be marketed in the United States as a drug product, a dietary supplement, or a food additive pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA has issued warning letters to firms marketing products containing 7-OH and has seized foods and dietary supplements containing the compound. In addition, as outlined in a 2023 Legal Sidebar, multiple states have imposed various regulations on kratom and its derivatives.

On July 1, 2026, DEA issued a new notice of its intent to temporarily control 7-OH in Schedule I. Specifically, the notice stated the intent to schedule substances that contain a concentration of "7-[OH] above a specified threshold, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers." The threshold was to be set at 0.05% 7-OH for the kratom plant. For articles produced synthetically or derived from the kratom plant "and further processed to manufacture alternative dosage forms such as extracts, concentrates, processed edibles, or pressed pills," the threshold was set to be either 0.05% 7-OH or 1 milligram of 7-OH in the article.

In a separate notice, DEA announced its intent to temporarily place in Schedule I the three 7-OH-related substances MP, MGM-15, and MGM-16, "including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers." The notice stated that MP is a "chemical rearrangement product" of 7-OH, MGM-15 is "derivative of 7-OH," and MGM-16 is a "highly potent opioid and shares a similar pharmacological profile with [MP] and MGM-15." It further stated that all three compounds are "potent opioids that share a similar pharmacological profile with 7-[OH]" and "produce analgesic effects that [are] more potent than morphine." The notice indicated that MP and MGM-15 are currently available in the consumer marketplace. While DEA had not found evidence of consumer sales of MGM-16, it had identified a vendor site listing it for future sale, and thus concluded that "to schedule MGM-15 without MGM-16 would create a regulatory loophole that manufacturers are already poised to exploit." The temporary scheduling of MP, MGM-15, and MGM-16 was not to be limited to substances containing threshold amounts of the compounds.

The two notices were published in the *Federal Register* on July 6, 2026. Each notice stated that a temporary scheduling order would be published in the *Federal Register* on or after August 5, 2026, would take effect on the date published, and would remain in effect for two years, subject to a possible one-year extension if permanent scheduling proceedings are pending. On August 26, 2026, DEA published a notice in the *Federal Register* finalizing the temporary scheduling of MP, MGM-15, and MGM-16, effective from August 26, 2026, until August 26, 2028. The same day, DEA extended the public comment period on the proposed temporary scheduling of 7-OH until September 10, 2026, "in response to a request for an extension to allow interested persons additional time to provide comments and input."

On October 14, 2026, DEA published a pair of notices in the *Federal Register*. DEA announced its intent to adopt a revised threshold approach for the temporary scheduling of 7-OH and MP. Specifically, DEA stated that it planned to adopt a recommendation from HHS to temporarily control 7-OH and MP in Schedule I to the extent that (1) the concentration of 7-OH, MP, or both substances combined is greater than 1 mg per gram in solid forms or 1 mg per milliliter for liquid preparations; *or* (2) the mass of mitragynine present divided by the mass of 7-OH, MP, or the two substances combined is less than 100. These thresholds would replace the thresholds proposed in July 2026 for temporary scheduling of 7-OH. For MP, it would limit control to products that exceed the thresholds, while currently any amount or concentration of the substance is controlled. The notice stated, "While the new threshold recommended by HHS would permit certain products to remain in the marketplace without being subject to schedule I controls, neither HHS nor DEA has made a finding that these substances are safe to use at below-threshold levels." It further stated that a temporary scheduling order would be published in the *Federal Register* on or after November 13, 2026. In a press release, DEA indicated that the August 2026

temporary scheduling of MP, which is not dependent on the concentration of the substance present, would remain in effect until a new temporary scheduling order is issued.

In a second October 14, 2026, notice, DEA conveyed its intent to temporarily schedule MGM-15 and MGM-16 as previously announced. DEA explained that it was publishing that notice of intent "only for the technical and procedural purpose of distinguishing MGM-15 and MGM-16 from [MP]."

Following finalization of the temporary scheduling of MP, MGM-15, and MGM-16, those substances will now be legally treated as Schedule I controlled substances for the duration of the temporary scheduling. They are thus subject to the applicable regulatory and criminal trafficking provisions of the CSA, and handling those substances outside the context of federally approved research studies is a federal crime. If the temporary scheduling of 7-OH or the revision of the scheduling of MP to include thresholds is finalized, 7-OH or MP (or a combination of the two substances) above the specified thresholds would be subject to the same regulations. Absent final scheduling action by DEA or Congress, however, 7-OH is not a controlled substance.

Considerations for Congress

DEA has previously used its temporary scheduling authority to control numerous substances other than 7-OH, MP, MGM-15, and MGM-16. One such instance that attracted significant interest from Congress was the control of certain fentanyl-related substances (FRS). As discussed in more detail in a Legal Sidebar, in 2018 DEA issued a temporary scheduling order controlling in Schedule I a large class of FRS defined by their chemical structure. DEA subsequently took permanent scheduling actions with respect to certain specific fentanyl analogues, including some FRS subject to the temporary scheduling order, but did not undertake permanent scheduling with respect to the full class of FRS.

The CSA requires DEA to make limited factual findings before temporarily scheduling a controlled substance, and more involved factual findings before permanent scheduling. It appears that DEA was unable to undertake permanent scheduling with respect to the full class of FRS because the class includes thousands of chemicals—and the effects, potential for abuse and dependence, and medical utility of many of those substances are unknown. By contrast, Congress is not bound by the CSA's fact-finding requirements when it schedules controlled substances via legislation. Congress enacted legislation to extend the temporary scheduling of FRS multiple times, then, in July 2025, enacted the Halt All Lethal Trafficking of Fentanyl Act, also known as the HALT Fentanyl Act, to permanently place the class of FRS in Schedule I.

While congressional action was required to make classwide scheduling of FRS permanent, it may not be necessary with respect to 7-OH, MP, MGM-15, and MGM-16. With four substances at issue rather than thousands, DEA may be able to undertake the required fact-finding for all the substances, though it remains to be seen whether DEA will temporarily control 7-OH or whether all the statutory factors for permanent scheduling will be satisfied for any of these substances.

If Congress seeks to change the status of 7-OH, MP, MGM-15, or MGM-16 under the CSA, it could do so by enacting legislation either before or after DEA takes administrative action. The END 7-OH Act (H.R. 8000), which was introduced in the 119th Congress before DEA issued the temporary scheduling notices discussed above, would permanently add 7-OH to Schedule I, "including its synthetic equivalents" but "not including 7-[OH] naturally contained in … kratom." The End Gas Station Heroin Act (S. 5383/H.R. 10272), introduced in August and September 2026, would amend the CSA to add 7-OH and MP to Schedule I, subject to certain exceptions for those compounds when they "naturally occur[ ]" in the kratom plant or "in a finished kratom product." The proposal would also apply Schedule I regulations to commercial activities, but not individual purchase or possession, of "a covered emerging synthetic opioid," defined to include certain "opioid receptor agonist[s], or partial agonist[s]" that are synthetically produced and more potent than morphine. Congress could also consider whether to control the kratom

plant itself or other compounds in kratom not subject to the temporary scheduling orders, such as mitragynine. Beyond the context of scheduling specific substances, Congress has the authority to amend the CSA to change general scheduling procedures, and could change the procedures or fact-finding requirements that apply to permanent or temporary administrative scheduling.

Congress could also enact legislation related to kratom or its derivatives outside the scope of the CSA. The Safe Sips Act of 2026 (H.R. 9913) would require the HHS Secretary to "establish a system for color coding the packaging" of certain drinks containing various intoxicating materials including "Kratom-related substance[s]." Proposals from the 118th and 117th Congresses, the Federal Kratom Consumer Protection Act (H.R. 5905/S. 3039) and the Federal Clarity for Kratom Consumers Act (H.R. 9634/S. 5316), would both have directed the FDA Commissioner to "hold at least one hearing that provides an open forum for the discussion on the current scientific data and information about safety and use of products containing kratom or kratom-derived products marketed as a food, dietary ingredient, or dietary supplement." Those bills would have established a Kratom Research Task Force charged with holding public meetings and reporting to Congress on all federally funded kratom-related research. They would also have imposed certain limits on the ability of the FDA Commissioner or the Secretary of Health and Human Services to regulate kratom, including but not limited to prohibiting "impos[ing] requirements on kratom or kratom-derived products that are more restrictive than the requirements for food, dietary supplements, and dietary ingredients that apply under [the FD&C Act]" and "requir[ing] kratom to undergo requirements for notification as a new dietary ingredient under section 413 of the [FD&C Act]."

Author Information

Joanna R. Lampe
Legislative Attorney

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