DEPARTM

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1644]

Schedules of Controlled Substances: Temporary Placement of Mitragynine Pseudoindoxyl, MGM-15, and MGM-16 in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Proposed amendment; notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule three 7-hydroxymitragynine-related substances (mitragynine pseudoindoxyl, MGM-15, and MGM-16), including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the Controlled Substances Act. When it is issued, the temporary scheduling order will impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle these three 7-hydroxymitragynine-related substances.

DATES: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION: The notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug

Enforcement Administration (DEA) intends to issue a temporary scheduling order[1] (in the form of a temporary amendment) to add three 7-hydroxymitragynine-related substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible, to schedule I under the Controlled Substances Act (CSA):

- Methyl (*E*)-2-((1′*S*,6′*S*,7′S)-6′-ethyl-4-methoxy-3-oxo-3′,5′,6′,7′,8′,8*a*′-hexahydro-2′*H*-spiro[indoline-2,1′-indolizine]-7′-yl)-3-methoxyacrylate (commonly known as mitragynine pseudoindoxyl),
- Methyl (*E*)-2-((2*S*,3*S*,7*aS*,12*aR*,12*bS*)-3-ethyl-7*a*-hydroxy-8-methoxy-1,2,3,4,6,7,7*a*,12,12*a*,12*b*-decahydroindolo[2,3-*a*]quinolizin-2-yl)-3-methoxyacrylate (commonly known as dihydro-7-hydroxymitragynine, or MGM-15),
- Methyl (*E*)- 2-((2*S*,3*S*,7*aS*,12*aR*,12b*S*)-3-ethyl-9-fluoro-7*a*-hydroxy-8-methoxy-1,2,3,4,6,7,7*a*,12,12*a*,12*b*-decahydroindolo[2,3-*a*]quinolizin-2-yl)-3-methoxyacrylate (commonly known as 9-fluoro-dihydro-7-hydroxymitragynine, or MGM-16).

The temporary scheduling order will be published in the *Federal Register* on or after [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Legal Authority

The CSA provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to public safety.[2] In

[1] Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this notice of intent adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.
[2] 21 U.S.C. 811(h)(1).

addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling for up to one year.[3]

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355.[4] The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of DEA (Administrator).[5]

Background

The CSA requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of this intent to issue a temporary scheduling order.[6] By letter dated December 15, 2025, the Administrator transmitted the required notice to place mitragynine pseudoindoxyl, MGM-15, and MGM-16 in schedule I on a temporary basis to the Assistant Secretary for Health of HHS (Assistant Secretary).[7] By letter dated January 20, 2026, the Assistant Secretary responded to this notice and advised that based on a review by the Food and Drug Administration (FDA), there were currently no investigational new drug applications (IND) or approved new drug applications (NDA) for mitragynine pseudoindoxyl, MGM-15, and MGM-16. The Assistant Secretary also stated that HHS had no objection to the temporary placement of these substances in schedule I of the CSA. Mitragynine pseudoindoxyl, MGM-15, and MGM-16 are not currently listed in any schedule under the CSA.

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to public safety, the Administrator must consider three of the eight

---

[3] 21 U.S.C. 811(h)(2).
[4] 21 U.S.C. 811(h)(1); 21 CFR part 1308.
[5] 28 CFR 0.100.
[6] 21 U.S.C. 811(h)(4).
[7] The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. *Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513, As Amended; Delegation of Authority*, 58 FR 35460 (July 1, 1993).

factors set forth in 21 U.S.C. 811(c): the substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to public health.[8] This consideration includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of mitragynine pseudoindoxyl, MGM-15, and MGM-16.[9]

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[10] Substances in schedule I have high potential for abuse, no currently accepted medical use in treatment in the United States,[11] and a lack of accepted safety for use under medical supervision.[12]

Three 7-Hydroxymitragynine-Related Substances: Mitragynine pseudoindoxyl, MGM-15, and MGM-16

The prevalence and misuse of *Mitragyna speciosa* (commonly known as kratom) and its

[8] 21 U.S.C. 811(c)(4)-(6), (h)(3).
[9] 21 U.S.C. 811(h)(3).
[10] 21 U.S.C. 811(h)(1).
[11] When finding schedule I placement on a temporary basis is necessary to avoid imminent hazard to the public, 21 U.S.C 811(h) does not require DEA to consider whether the substance has a currently accepted medical use in treatment in the United States. Nonetheless, there is no evidence suggesting that mitragynine pseudoindoxyl, MGM-15, and MGM-16 have a currently accepted medical use in treatment in the United States. First, DEA looks to whether the drug or substance has FDA approval. When no FDA approval exists, DEA has traditionally applied a five-part test to determine whether a drug or substances has a currently accepted medical use: (1) the drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available. *Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics v. Drug Enforcement Admin.*, 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA applied the traditional five-part test and concluded the test was not satisfied. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care providers operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this notice of intent, there is no evidence that health care providers have widespread experience with medical use of mitragynine pseudoindoxyl, MGM-15, and MGM-16, or that the use of these substances is recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied. In HHS' letter dated January 20, 2026, HHS advised DEA that there were currently no approved new drug applications or investigational new drug applications for mitragynine pseudoindoxyl, MGM-15, and MGM-16. Additionally, HHS noted it had no objections to the temporary placement of these substances in schedule I of the CSA.
[12] 21 U.S.C. 812(b)(1).

psychoactive alkaloids, including mitragynine and 7-hydroxymitragynine, have led to the proliferation of commercial products containing opioids chemically synthesized from mitragynine or 7-hydroxymitragynine. In recent years, mitragynine pseudoindoxyl, which is a chemical rearrangement product of 7-hydroxymitragynine, and MGM-15, which is a derivative of 7-hydroxymitragynine, have recently emerged on the *Mitragyna speciosa* consumer markets. MGM-16 is a highly potent opioid and shares a similar pharmacological profile with mitragynine pseudoindoxyl and MGM-15. The chemical scaffolds of mitragynine or 7-hydroxymitragynine were used in scientific research to develop mitragynine pseudoindoxyl, MGM-15, or MGM-16 via chemical modifications of purified isolates. Evidence from the *Mitragyna speciosa* retail markets demonstrates that mitragynine pseudoindoxyl and MGM-15 have transitioned from experimental substances studied in research to widely available commercial products. These products are commonly sold in different forms such as powders, tablets, and liquid shots. This is a significant evolution from the traditional administration of *Mitragyna speciosa*, which was once restricted to either chewing raw leaves or steeping the leaves into water decoctions and teas.

These products are sold under numerous brand names like Kama, Hydroxie, Fruity Perks, and Happie Tabs[13], and they are easily purchased on the Internet, as well as in gas stations, corner shops, and vape shops. These products are available in consumer-friendly forms to include flavored chewable tablets, which increases their appeal to a broader demographic. Also, the aggressive marketing of these semi-synthetic opioids (mitragynine pseudoindoxyl, MGM-15) as "precision-formulated products," "botanical extracts," or as "mood boosters" for the treatment of health conditions is deeply concerning. The branding creates a false sense of safety for unknowing consumers who may equate the term "botanical" with lower risk. Furthermore, there is paucity of data on quality control or standardized dosage available for these products, making their use especially dangerous.

[13] The list of brand names is illustrative, non-exhaustive, and provided solely as market context.

Mitragynine pseudoindoxyl, MGM-15, and MGM-16 are potent opioids that share a similar pharmacological profile with 7-hydroxymitragynine. Available pharmacology data demonstrate that mitragynine pseudoindoxyl, MGM-15, and MGM-16 exhibit strong affinity for the mu-opioid receptor (MOR) and function as MOR agonists.[14,15] Data from preclinical studies show that these substances produce analgesic effects that is more potent than morphine.[16] oBecause mitragynine pseudoindoxyl, MGM-15, and MGM-16 are potent MOR agonists, they pose similar health risks as other mu-opioid agonists (i.e., morphine and fentanyl), including physical and psychological dependence, and respiratory depression.

A scan of retail data on the Internet shows that vendors explicitly market mitragynine pseudoindoxyl and MGM-15 for their "clean and powerful" opioid-receptor activation, utilizing deceptive terminology to target individuals seeking alternatives to pharmaceutical opioids. These combinations and marketing strategies pose significant safety risks to unsuspecting consumers who use these products by exposing them to high doses of opioids. Recently, reports have confirmed the positive identification of mitragynine pseudoindoxyl and MGM-15 in toxicology cases in the United States, and evidence demonstrates that these substances are being misused. The lack of clinical data regarding their safety and efficacy, coupled with the risk of life-threatening respiratory depression and addiction, underscores the danger of marketing these unapproved, highly potent opioids under the guise of therapeutic or wellness products.

While no evidence supports the presence of MGM-16 on the *Mitragyna speciosa* consumer market, its profile as a highly potent opioid that is structurally related to 7-

---

[14] Matsumoto, K., Narita, M., Muramatsu, N., Nakayama, T., Misawa, K., Kitajima, M., Tashima, K., Devi, L. A., Suzuki, T., Takayama, H., & Horie, S. (2014). Orally active opioid μ/δ dual agonist MGM-16, a derivative of the indole alkaloid mitragynine, exhibits potent antiallodynic effect on neuropathic pain in mice. *The Journal of Pharmacology and Experimental Therapeutics*, 348(3):383-392.

[15] Yamamoto, L. T., Horie, S., Takayama, H., Aimi, N., Sakai, S., Yano, S., Shan, J., Pang, P. K., Ponglux, D., & Watanabe, K. (1999). Opioid receptor agonistic characteristics of mitragynine pseudoindoxyl in comparison with mitragynine derived from Thai medicinal plant Mitragyna speciosa. *General Pharmacology*, 33(1):73-81.

[16] Váradi, A., Marrone, G. F., Palmer, T. C., Narayan, A., Szabó, M. R., Le Rouzic, V., Grinnell, S. G., Subrath, J. J., Warner, E., Kalra, S., Hunkele, A., Pagirsky, J., Eans, S. O., Medina, J. M., Xu, J., Pan, Y. X., Borics, A., Pasternak, G. W., McLaughlin, J. P., & Majumdar, S. (2016). Mitragynine/Corynantheidine Pseudoindoxyls As Opioid Analgesics with Mu Agonism and Delta Antagonism, Which Do Not Recruit β-Arrestin-2. *Journal of Medicinal Chemistry*, 59(18):8381-8397.

hydroxymitragynine lends itself as an attractive substitute that could emerge on the illicit drug market. MGM-16 is synthetically manufactured for research purposes and is not approved for any clinical indication in the United States. DEA's investigation of publicly available information, including popular online platform, revealed that at least some individuals intend to abuse MGM-16. Recent online surveillance of a vendor site[17] lists MGM-16 for upcoming sale. The sale of products containing mitragynine pseudoindoxyl, and MGM-15, and the potential sale of MGM-16 poses an imminent hazard to public safety.

Available data and information for mitragynine pseudoindoxyl, MGM-15, and MGM-16, summarized below, indicate that these substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. DEA's three-factor analysis is available in its entirety under "Supporting and Related Material" of the public docket for this action at *www.regulations.gov* under Docket Number DEA-1644.

Factor 4. History and Current Pattern of Abuse

Mitragynine pseudoindoxyl, MGM-15, and MGM-16 are synthetic derivatives of the indole alkaloids, mitragynine or 7-hydroxymitragynine, of the *Mitragyna speciosa* plant. Unlike the indole alkaloids mitragynine and 7-hydroxymitragynine, which are naturally occurring in the plant, mitragynine pseudoindoxyl, MGM-15, and MGM-16 are produced through synthetic modifications of purified mitragynine isolates or 7-hydroxymitragynine.[18] The chemical scaffolds of mitragynine or 7-hydroxymitragynine were used in scientific research to develop novel mitragynine pseudoindoxyl, MGM-15, and MGM-16. The first mention of mitragynine pseudoindoxyl in scientific literature dates to 1974 when mitragynine pseudoindoxyl was isolated as a metabolite from bio transformed mitragynine. In 2014, as part of a drug discovery

[17] MGM Series Guide: Science of MGM-15 Alkaloids | Getwell Depot. https://getwelldepot.com/mgm/. Accessed April 9, 2026. (Web content subsequently modified or removed; hardcopy preserved in DEA administrative record)
[18] *Id*, 13;14; Takayama, H., Ishikawa, H., Kurihara, M., Kitajima, M., Aimi, N., Ponglux, D., Koyama, F., Matsumoto, K., Moriyama, T., Yamamoto, L. T., Watanabe, K., Murayama, T., & Horie, S. (2002). Studies on the synthesis and opioid agonistic activities of mitragynine-related indole alkaloids: discovery of opioid agonists structurally different from other opioid ligands. *Journal of Medicinal Chemistry*, 45(9):1949–1956.

research, MGM-15 and MGM-16 were developed as potent opioid agonists, with potential therapeutic utility for pain.[19]

Market Emergence and Designer-Drug Patterns

The first confirmed appearance of mitragynine pseudoindoxyl in consumer products was reported in 2024.[20] The emergence of MGM-15 in commercially available products was in September 2025.[21] The introduction of these substances into the *Mitragyna speciosa* consumer market follows a classic pattern of new designer drugs, where packaging appears like those of designer novel psychoactive substances and are often advertised as "sold strictly for laboratory, botanical, and research purposes only" and "not intended for human consumption."[22] A study on products sold online containing mitragynine pseudoindoxyl showed that of the 51 total products sold online, 35 had an appealing flavor (e.g., various berry, mint, watermelon, pink lemonade, candy apple, grape, citrus, mango, pistachio, and vanilla bean), and 32 of the products had packaging that was formulated using bright colors. Seventy-six percent (39 of 51) of these products were chewable tablets, 18 percent were liquids (9 of 51), and the remaining three were either dried ice cream cones with ice cream (two products) or a chocolate bar (one product).[23] Many of the products typically feature serving sizes that require consumers to split tablets or doses.

---

[19] *Id*, 13.
[20] Hill, K., Boyer, E. W., Grundmann, O., & Smith, K. E. (2025). De facto opioids: Characterization of novel 7-hydroxymitragynine and mitragynine pseudoindoxyl product marketing. *Drug and Alcohol Dependence*, 272: 112701; Krotulski, A. J.; Denn, M.T., Brower, J. O., Papsun, D. M., & Logan, B. K. (2025). Evaluation of Commercially Available Smoke Shop Products Marketed as "7-Hydroxy Mitragynine" & Related Alkaloids, Center for Forensic Science Research and Education, United States; Vadiei, N., Evoy, K. E., & Grundmann, O. (2025). The Impact of Diverse Kratom Products on Use Patterns, Dependence, and Toxicity. *Current Psychiatry Reports*, 27(10):584-592.
[21] Gour, A., Mukhopadhyay, S., Henderson, A., Awad, A., Seabra, M. A., Pullman, M., Leon, F., Cutler, J. C., McCurdy, C. R., & Sharma A. (2025). From Kratom to Semi-Synthetic Opioids: The Rise and Risks of MGM-15. *Drug Testing and Analysis,* 17(12):2384-2389.
[22] *Id*, 24.
[23] White, C. M., Belcourt, J., & Sedensky, A. (2025). A Descriptive Assessment of Products Containing the Opioid Receptor Stimulator Mitragynine Pseudoindoxyl. *Substance Use & Misuse*, 60(12):1950–1954.

Current Patterns of Use

Users seek these 7-hydroxymitragynine-related products for their psychoactive effects and products are often advertised as mood enhancers or alternative to prescription opioid analgesics (*see* Factor 5). These products are commonly sold in different product forms, such as powders, tablets, or liquid shots, which is a sharp contrast from the traditional mode of administration of *Mitragyna speciosa*, which was confined to either water decoctions or brewed into tea or chewing of fresh leaves. A review of vendor websites[24] show that these products are explicitly marketed as "potent" and "fast-acting" substances and sold at low prices. For example, mitragynine pseudoindoxyl and MGM-15 tablets are sold in varying fruit flavors and in bright colors, and prices vary from about $2-4 per tablet or $34.99 per pack (single pack and 10-pack bulk). Of great concern to DEA is that the price of these products may facilitate high-frequency and rapid escalation of use (*see* Table 1). Further, open-source signal detection demonstrates that users are seeking MGM-16 with the intent to abuse.[25]

Table 1: Retail Distribution of Mitragynine Pseudoindoxyl and MGM-15 Products

Brand	**Product Form**	**Stated Concentration**	**Marketing Narrative**
Overseas Organix	Extract Tablets	15 mg MGM-15	"Ultra-potent ……for experienced users who want strong, consistent effects with small serving sizes. available. 4–6-hour duration."
Majestic White	Sublingual Tablet	3.5 mg MGM-15 (+50 mg MIT)	"Next generation kratom formulation.,. Its sublingual design allows for fast absorption and precise serving control."
MGM-15 Tablets - Berries	Chewable Tablets (Berries)	30 mg MGM-15	"This single, pocket-ready tablet delivers consistent strength without the guesswork. Each tablet offering a fast-acting, predictable experience you can count on. To dissolve smoothly for quick onset."
Kama Pseudoindoxyl	Extract tablet	500 mg Kama 7-Hydroxy + Pseudo extracts	"Stop settling for weak kratom products….Enjoy great flavor and precise dosing without the guesswork."

[24] Market Audit of Online Retailers, Jan. 2026.
[25] Can anyone help with the MGM 16 rumors?r/KratomKorner. https://www.reddit.com/r/KratomKorner/comments/1kpz2u3/can_anyone_help_with_the_mgm_16_rumors/?rdt=48097. Accessed April 9, 2026.

Kream	Liquid Shot	90 mg 7-Hydroxy +Pseudo	"Tired of slow supplements that give you a crash? delivering fast-acting effects and calm mental clarity in a discreet little bottle. This clean, lab-tested liquid shot features 7-hydroxy and pseudo in a citrus formula for consistent potency, making it easy to find focus and wellness without waiting long"

The shift from natural leaf decoctions of *Mitragyna speciosa* to flavored, standardized, and high-potency semi-synthetic substances suggests an intentional market strategy to maximize consumer appeal and sale of products with rapid onset of effects. The use of "research chemical" labeling, a common tactic to bypass regulatory oversight, for flavored chewable products further demonstrates a pattern to reach a broader consumer demographics.

Factor 5. Scope, Duration, and Significance of Abuse

The abuse of mitragynine pseudoindoxyl and MGM-15 is concerning due to their high opioid potency and commercial availability. Mitragynine pseudoindoxyl and MGM-15 products are sold in formulations that facilitate ease of use, bypass the traditional, lower-alkaloid preparation (chewing leaves or drinking tea) and provide a highly potent effect that mimics classical opioids such as morphine.

Deceptive Branding and Market Infiltration

Analysis of marketed mitragynine pseudoindoxyl products revealed misleading marketing strategies with claims that the products are "kratom." Available information on vendor website indicates that the concentrated alkaloid products often contain more than one alkaloid with opioid activity (e.g., mitragynine and MGM-15 or 7-hydroxymitragynine and mitragynine pseudoindoxyl). These substance combinations and marketing practices pose significant safety risk to unsuspecting consumers by exposing them to high doses of opioids (*see* Table 1). It is known that repeated use of opioids can lead to psychological and physical dependence. In fact, data show that chronic use of 7-hydroxymitragynine has sent users to

opioid detox clinic and the need for opioid use disorder medication.[26] Furthermore, these products are labeled for "strong mood enhancement" and "analgesic properties." Finally, the presence of these products containing mitragynine pseudoindoxyl and MGM-15 is deeply concerning because the identity, purity, and quality of these products' formulation are uncertain, thus presenting additional safety concerns for unsuspecting users. The potential presence of MGM-16 in designer drug products would have similar concerns.

A study of products sold as mitragynine pseudoindoxyl over the internet found that the 51 unique products sold online as mitragynine pseudoindoxyl were marketed in child-appealing forms and contained other opioid alkaloids, with limited consumer safety information. The serving size varied and alkaloid concentrations for these marketed products were often higher than those in naturally occurring *Mitragyna speciosa* leaves. The analysis revealed that among the products sampled, 71 percent featured a combination of mitragynine pseudoindoxyl and 7-hydroxymitragynine, while 24 percent contained mitragynine pseudoindoxyl only. The remaining 6 percent contained combination of mitragynine pseudoindoxyl and other hydroxymitragynine forms (8-hydroxymitragynine or 11-hydroxymitragynine).[27]

National E-commerce

Data from online sources show that the availability of mitragynine pseudoindoxyl and MGM-15 are not isolated to a single region but have rapidly spread across the United States. Products containing mitragynine pseudoindoxyl and MGM-15 are sold on the internet and are delivered to most states where there are currently no kratom use restrictions, suggesting national distribution network facilitated by online sales and mass-market retail channels. The significance of the abuse of mitragynine pseudoindoxyl and MGM-15 is underscored by the potent opioid pharmacological profile of these substances and the specific health warnings

---

[26] Wightman, R. S., & Hu, D. (2025). A Case of 7-OH Mitragynine Use Requiring Inpatient Medically Managed Withdrawal. *Journal of Addiction Medicine*, 10.1097/ADM.0000000000001558. Advance online publication.

[27] Wilson, L. L., Chakraborty, S., Eans, S. O., Cirino, T. J., Stacy, H. M., Simons, C. A., Uprety, R., Majumdar, S., & McLaughlin, J. P. (2021). Kratom Alkaloids, Natural and Semi-Synthetic, Show Less Physical Dependence and Ameliorate Opioid Withdrawal. *Cell Mol Neurobiol*., 41(5):1131-1143. doi: 10.1007/s10571-020-01034-7.

acknowledged even by those who are marketing the substances. Vendor descriptions listed below provide insight into the duration and pattern of use that characterizes the abuse of these compounds:

Sustained Effect: The duration of effects is reported to last "several hours."[28] This prolonged duration increases the likelihood of cumulative effects and potential for toxicity if doses are repeated.

Deceptive Marketing for Medical Conditions: Despite having no FDA-approved medical use, these products are explicitly marketed for "easing stress and tension," "internal calm and reduced restlessness," and as a "mental clarity." [29] This marketing encourages individuals with legitimate medical needs to utilize potent, unlawful opioids as self-treatment.

Deceptive "Natural" Branding: Vendors frequently frame these substances as "clean and powerful" alternatives to traditional kratom. This branding is used to minimize the perceived risk of what are highly potent semi-synthetic opioid agonists.

Deceptive Safety Profiles: While products are marketed as a "midday stress relief" or "mental reset," the inclusion of warnings for lethal respiratory depression on retail sites confirms that the products possess a toxicity profile identical to scheduled opioids.

Low Barrier to Entry: The use of "fruity" flavors and "chewable" formats (e.g., Fruity Perks) suggests an effort to appeal to a broader, potentially younger demographic, significantly increasing the scope of potential abuse.

Forensic Surveillance and Identification

---

[28] *See* Pseudoindoxyl Chewable Tablets - Red Vein - Advanced Alkaloids Descriptions, https://cbdamericanshaman.com/pseudoindoxyl-chewable-tablets-red-vein-advanced-alkaloids. Accessed January 2026.

[29] *See* Dozo Perks Extremely Potent Pseudoindoxyl Chewable Tablet Grape 100mg Per Tablet, https://pureleafkratom.com/products/dozo-perks-100mg-pseudoindoxyl-grape-chewable-tablets-4ct.html. Accessed January 2026.

According to the National Forensic Laboratory Information System (NFLIS)[30] database, which collects drug identification results from drug cases submitted to and analyzed by Federal State and local forensic laboratories, there has been one report of mitragynine pseudoindoxyl in New York (queried February 26, 2026). Further, recent monographs[31] by Center for Forensic Science Research and Education (CFSRE), report that mitragynine pseudoindoxyl (n > 10) and MGM-15 (n = 2) have been detected in at least 12 drug materials. MGM-15 was detected as a tan solid drug that originated from New England, and those involving mitragynine pseudoindoxyl (pills and tablets) initially originated from Pennsylvania and Illinois.

The paucity or lack of seizure data for some of these 7-hydroxymitragynine-related substances as reported in forensic laboratories casework may be due to lack of readily available analytical reference standards and other analytic challenges. Because these are new substances, it often takes time for forensic laboratories to develop and validate the necessary testing methods required for substance identification. Specifically, mitragynine pseudoindoxyl is an oxidative metabolite of 7-hydroxymitragynine, and such closely related compounds require specific method and instrumentation for accurate identification. Also, since these 7-hydroxymitragynine-related substances are not federally controlled under the CSA, some forensic laboratories may not analyze and track encounters of non-controlled substances and thus reporting could be limited.

The population likely to abuse mitragynine pseudoindoxyl, MGM-15, and MGM-16 appear to be the same as those abusing *Mitragyna speciosa* and prescription opioid analgesics.

---

[30] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle the nation's drug analysis cases. NFLIS-Drug participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is currently 98.5 percent. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV,* 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS data was queried on December 5, 2025.

[31] https://www.cfsre.org/nps-discovery/monographs/mitragynine-pseudoindoxyl. Report Date- November 7, 2025. Accessed January 9, 2026; https://www.cfsre.org/nps-discovery/monographs/dihydro-7-hydroxy-mitragynine. Report Date- November 11, 2025. Accessed January 9, 2026.

According to data from the National Survey on Drug Use and Health (NSDUH),[32] as of 2021, an estimated 1.7 million people aged 12 years or older used kratom in the past year. The highest users were among adults aged 26 or older (1.4 million people). The analysis of 2019 NSDUH survey data showed that kratom users base predominately non-Hispanic White and male. The survey finding also revealed a link between kratom use and substance use disorder, particularly nonmedical prescription opioid use disorder, indicative of a strong trend of use for self-managing opioid dependence.[33]

Factor 6. What, If Any, Risk There Is to Public Health

Mitragynine pseudoindoxyl, MGM-15, and MGM-16 function as potent MOR agonist. This mechanism of action is inherently associated with high potential of abuse, physical dependence, and psychological dependence, consistent with the effects of controlled schedule I and II opioid substances. As of early 2026, mitragynine pseudoindoxyl and MGM-15 products are sold in smoke shops, gas stations, and through numerous online marketplaces, often marketed alongside traditional supplements, which mask their potent opioid nature. Data from preclinical studies demonstrate that mitragynine pseudoindoxyl is about 100 times more potent than mitragynine at the MOR, MGM-15 and MGM-16 are about 50 and 240 times more potent than morphine in animal models, respectively.[34] Because of the potency of these compounds, they can be abused in smaller, concentrated doses. It has been demonstrated that mitragynine pseudoindoxyl may cause development of signs of opioid physical dependence after chronic use

---

[32] The NSDUH, formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by the Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of nonmedical use of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals. The NSDUH provides yearly national and state level estimates of drug abuse, and includes prevalence estimates by lifetime (i.e., ever used), past year, and past month abuse or dependence.

[33] Palamar, J. J. (2021). Past-Year Kratom Use in the U.S.: Estimates From a Nationally Representative Sample. *Am J Prev Med.,* 61(2):240-245: Rogers, J. M., Smith, K. E., Strickland, J. C., & Epstein, D. H. (2021). Kratom Use in the US: Both a Regional Phenomenon and a White Middle-Class Phenomenon? Evidence From NSDUH 2019 and an Online Convenience Sample. *Frontiers in Pharmacology*, 12:789075.

[34] *Id* 13-14.

in rodents. Pre-clinical studies demonstrated that chronic twice-daily administration of mitragynine pseudoindoxyl in rodents induces signs of opioid physical dependence and withdrawal symptoms in morphine addiction rodent models as evidenced by increased diarrhea, jumping, and rearing frequency occurring when naloxone was administered or when treatment with this alkaloid was tapered.[35]

These products are easily accessible in unregulated retail environments often with no age restrictions, amplifying public health concerns, particularly to vulnerable populations. Vendor descriptions provide insight into the public health threat posed by the abuse of these compounds:

Rapid Onset: Marketing materials for mitragynine pseudoindoxyl products emphasize a "quick onset," typically occurring within 10 to 60 minutes, often described as a "wave of calm clarity," "dual-action formula featuring 100mg per piece for maximum potency and a fast-acting hit."[36]

Sustained Effect: The duration of effects is reported to last "several hours."[37] This prolonged duration increases the likelihood of cumulative effects and potential for toxicity if doses are repeated.

Potency Information: Marketing information of an MGM-15 product indicates this product contains a very large amount of MGM-15 "105 mg total per bottle,"[38] which, given its extreme opioid potency, presents a significant threat to public health.

Opioid Receptor Activation: Marketing materials explicitly state that these compounds directly activate opioid receptors and are "full agonist at mu receptors," providing effects that mirror analgesic and stimulant effects ("pain relief and mood enhancement").[39]

---

[35] Wilson, L. L., Chakraborty, S., Eans, S. O, Cirino, T. J., Stacy, H. M., & Simons, C. A., Uprety, R., Majumdar, S., & McLaughlin, J. P. (2021). Kratom Alkaloids, Natural and Semi-Synthetic, Show Less Physical Dependence and Ameliorate Opioid Withdrawal. *Cell Mol Neurobiol.*, 41(5):1131-1143.

[36] See Kama Kratom https://greatcbdshop.com/product-category/brands/kama-kratom/ and Pure Leaf Kratom **h**ttps://pureleafkratom.com/kama-kratom/. Accessed March 2026.

[37] *Id*. 26

[38] MGM-15 | 7 count - 15mg tablets (105mg total) – Can Vertex Bioscience Accessed March 2026. (Web content subsequently modified or removed; hardcopy preserved in DEA administrative record)

[39] *Id*.

Acknowledgment of Severe Risks: Notably, vendors acknowledge significant public health risks, advising users to monitor for "habit-forming behavior," "high euphoria," "dependence," "overdose," and "death".[40] The mention of overdose and death is a significant indicator of the hazard these substances pose.

As with any MOR agonist, the potential health and safety risks for users of 7-hydroxymitragynine-related substances are high. Mitragynine pseudoindoxyl, MGM-15, and MGM-16 abuse carry a high risk of cardiotoxicity, hepatic and renal toxicity, respiratory depression, neurological effects, and physical dependence and withdrawal. According to data from poison control centers, from January to July 2025, there have been 1,690 exposure calls involving kratom, a significant increase from 2024 exposure calls. According to data from DEA Toxicology Testing Program (DEA TOX),[41] between February 2025 - February 2026, mitragynine pseudoindoxyl has been identified in at least 31 overdose cases, of which 25 were fatal events. Recent monographs by CFSRE report that mitragynine pseudoindoxyl (n >10) and MGM-15 (n =1) have been detected in at least 12 toxicology cases. MGM-15 was co-identified with mitragynine, 7-hydroxymitragynine, and trace ketamine. Mitragynine pseudoindoxyl was co-identified with other kratom alkaloids.

The sale of products with combination of high-potency opioids, explicit marketing for medical ailments, and the acknowledged potential for life-threatening respiratory depression and addiction highlights the danger posed by mitragynine pseudoindoxyl and MGM-15. While mitragynine pseudoindoxyl and MGM-15 have already been identified in fatal toxicological screening, the pharmacological profile of MGM-16 presents a significant health risk. As previously mentioned, MGM-16 is an opioid agonist with approximately 240-times the antinociceptive potency of morphine in animal studies. Recent online surveillance of a vendor

---

[40] *Id*; See 7-OHFactory30mg MGM-15 Tablets - Berries. https://www.7ohfactory.com/products/30mg-mgm-15-tablets-berries Accessed March 2026.

[41] DEA TOX is a surveillance program that aims to detect novel psychoactive substances in fatal and nonfatal overdose cases within the United States. From these cases, biological samples, as well as drug paraphernalia (on limited occasions), are submitted for analysis by hospitals, medical examiners, poison centers, and law enforcement nationwide. Query date 2/27/2026.

site[42] lists MGM-16 for upcoming sale. This transition from a research grade chemical to an accessible consumer product, combined with its opioid mechanism of action, underscores its potential as a highly attractive but lethal substitute. Thus, to schedule MGM-15 without MGM-16 would create a regulatory loophole that manufacturers are already poised to exploit. Its inclusion is necessary to prevent a market shift toward an even more potent derivative that poses a significant risk of respiratory depression.

Finding of Necessity of Schedule I Placement to Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of mitragynine pseudoindoxyl, MGM-15, and MGM-16 pose an imminent hazard to public safety. DEA is not aware of any currently accepted medical uses for mitragynine pseudoindoxyl, MGM-15, and MGM-16 in the United States. A substance meeting the statutory requirements for temporary scheduling, found in 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for mitragynine pseudoindoxyl, MGM-15, and MGM-16 indicate that these substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

As required by 21 U.S.C. 811(h)(4), the Administrator notified the Assistant Secretary, via letter dated December 15, 2025 of DEA's intention to temporarily place mitragynine pseudoindoxyl, MGM-15, and MGM-16 in schedule I. In a letter dated January 20, 2026, the Assistant Secretary for Health had no objection to the temporary placement of these substances in schedule I.

---

[42] MGM Series Guide: Science of MGM-15 Alkaloids | Getwell Depot. https://getwelldepot.com/mgm/. Accessed April 9, 2026. (Web content subsequently modified or removed; hardcopy preserved in DEA administrative record)

Conclusion

This notice of intent provides the 30-day notice pursuant to 21 U.S.C. 811(h)(1) of DEA's intent to issue a temporary scheduling order. In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule mitragynine pseudoindoxyl, MGM-15, and MGM-16 in schedule I of the CSA, and finds that placement of these substances in schedule I of the CSA is necessary in order to avoid an imminent hazard to the public's safety.

The temporary placement of mitragynine pseudoindoxyl, MGM-15, and MGM-16 in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Because the Administrator hereby finds that this temporary scheduling order is necessary to avoid an imminent hazard to public safety, it will take effect on the date the order is published in the *Federal Register* and remain in effect for two years, with a possible extension of an additional year, pending completion of the regular (permanent) scheduling process.[43] The Administrator intends to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon publication of the temporary order, mitragynine pseudoindoxyl, MGM-15, and MGM-16 will then be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession.

The CSA sets forth specific criteria for scheduling drugs or other substances. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557.[44] The regular scheduling process of formal rulemaking affords

[43] 21 U.S.C. 811(h)(1) and (2).
[44] 21 U.S.C. 811.

interested parties appropriate process and the government any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review.[45] Temporary scheduling orders are not subject to judicial review.[46]

Regulatory Analyses

The CSA provides for expedited temporary scheduling actions where necessary to avoid an imminent hazard to public safety. Under 21 U.S.C. 811(h)(1), the Administrator (as delegated by the Attorney General) may, by order, temporarily schedule substances in schedule I. Such orders may not be issued before the expiration of 30 days from: (1) the publication of a notice in the *Federal Register* of the intent to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS, as delegated by the Secretary of HHS.[47]

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, including the requirement of a publication in the *Federal Register* of a notice of intent, the notice-and-comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. The APA expressly differentiates between an order and a rule, as it defines an "order" to mean a "final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making*."[48] This contrasts with permanent scheduling actions, which are subject to formal rulemaking procedures done "on the record after opportunity for a hearing," and final decisions that conclude the scheduling process and are subject to judicial review.[49] The specific language chosen by Congress indicates its intent that DEA issue *orders* instead of proceeding by rulemaking when temporarily scheduling substances. Given that Congress

[45] 21 U.S.C. 877.
[46] 21 U.S.C. 811(h)(6).
[47] 21 U.S.C. 811(h)(1).
[48] 5 U.S.C. 551(6) (emphasis added).
[49] 21 U.S.C. 811(a) and 877.

specifically requires the Administrator (as delegated by the Attorney General) to follow rulemaking procedures for *other* kinds of scheduling actions,[50] it is noteworthy that, in section 811(h)(1), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

Even assuming that this notice of intent is subject to the notice-and-comment requirements of the APA, the Administrator finds that there is good cause to forgo the those requirements pursuant to 5 U.S.C. 553(b)(B), as any further delays in the process for issuing temporary scheduling orders would be impracticable and contrary to the public interest given the manifest urgency to avoid an imminent hazard to public safety.

Although DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice-and-comment requirements of the APA, DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator took into consideration comments submitted by the Assistant Secretary in response to the notice that DEA transmitted to the Assistant Secretary pursuant to such subsection.

Further, DEA believes that this temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking. As discussed above, DEA is issuing this notice of intent pursuant to DEA's authority to issue a temporary scheduling order.[51] Therefore, in this instance, since DEA believes this temporary scheduling action is not a "rule," it is not subject to the requirements of the RFA when issuing this temporary action.

In accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this action is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and

[50] *See* 21 U.S.C. 811(a).
[51] 21 U.S.C. 811(h)(1).

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. Because this is not a rulemaking action, this is not a significant regulatory action as defined in Section 3(f) of E.O. 12866. In addition, DEA scheduling actions are not subject to either E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

This action will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 13132, it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. In § 1308.11 add paragraphs (h)(88) through (90) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

* * * * * * *

(88) Methyl (*E*)-2-((1′*S*,6′*S*,7′S)-6′-ethyl-4-methoxy-3-oxo-3′,5′,6′,7′,8′,8*a*′-hexahydro-2′*H*-spiro[indoline-2,1′-indolizine]-7′-yl)-3-methoxyacrylate (commonly known as mitragynine pseudoindoxyl)	9672
(89) Methyl (*E*)- 2-((2*S*,3*S*,7*aS*,12*aR*,12*bS*)-3-ethyl-7*a*-hydroxy-8-methoxy-1,2,3,4,6,7,7*a*,12,12*a*,12*b*-decahydroindolo[2,3-*a*]quinolizin-2-yl)-3-methoxyacrylate (commonly known as MGM-15; also known as dihydro-7-hydroxymitragynine;)	9673
(90) Methyl (*E*)- 2-((2*S*,3*S*,7*aS*,12*aR*,12b*S*)-3-ethyl-9-fluoro-7*a*-hydroxy-8- methoxy-1,2,3,4,6,7,7*a*,12,12*a*,12*b*-decahydroindolo[2,3-*a*]quinolizin-2-yl)-3-methoxyacrylate (commonly known as MGM-16; also known as 9-fluoro derivate of 7-hydroxymitragynine;)	9674
* * * * * * *	

* * * * *

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on July 1, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

[FR Doc. 2026-13581 Filed: 7/1/2026 4:15 pm; Publication Date: 7/6/2026]