DEPARTM

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1570]

Schedules of Controlled Substance: Temporary Placement of 7-Hydroxymitragynine Above a Specified Threshold 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 7-hydroxymitragynine above a specified threshold, including its 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 7-hydroxymitragynine above a specified threshold.

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 7-hydroxymitragynine[2] above a specified threshold described herein, including its 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). The specified threshold for 7-hydroxymitragynine was adapted from the definition used by the Department of Health and Human Services (HHS),[3] which is described as follows:

(A) *Any botanical material of the plant Mitragyna speciosa, also known as kratom, and contains more than 0.050 percentage of 7-hydroxymitragynine on a dry weight basis, or*

(B) *Any alternative article to that described in (A), that is:*

i. *Resulting from synthetic methods and containing 7-hydroxymitragynine present in amounts greater than 0.050 percentage by weight/weight, weight/volume, or volume/volume or greater than 1.00 milligram of 7-hydroxymitragynine in the article, or*

ii. *Material derived from Mitragyna speciosa and further processed to manufacture alternative dosage forms such as extracts, concentrates, processed edibles, or pressed pills, and which may have materials that have been exposed to chemical, thermal, or other methods leading to chemical transformations that result in 7-hydroxymitragynine present in amounts greater than 0.050 percentage by weight/weight, weight/volume, or*

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[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] Chemical name: Methyl (*E*)-2-((2*S*,3*S*,7*aS*)-3-ethyl-7*a*-hydroxy-8-methoxy-1,2,3,4,6,7,7*a*,12*b*-octahydroindolo[2,3-*a*]quinolizin-2-yl)-3-methoxyacrylate (also known as: (αE,2*S*,3*S*,7a*S*,12b*S*)-3-ethyl-l,2,3,4,6,7,7a,12b-octahydro-7a-hydroxy-8-methoxy-a-(methoxymethylene)-indolo[2,3-*a*]quinolizine-2-acetic acid, methyl ester).

[3] In a letter dated July 28, 2025, pursuant to 21 U.S.C. 811(b) and (c), HHS provided to DEA a scientific and medical evaluation entitled "Basis for the Recommendation to Control 7-Hydroxymitragynine and its Salts, As Present in excess of the Specified Threshold Limit Described Herein, in Schedule I of the Controlled Substances Act."

volume/volume, or greater than 1.00 milligram of 7-hydroxymitragynine in the article.

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.[4] In 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.[5]

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 (FD&C Act), 21 U.S.C. 355.[6] The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of DEA (Administrator).[7]

Background

The CSA requires the Administrator to notify the Secretary of HHS of this intent to issue a temporary scheduling order.[8] By letter dated February 24, 2026, the Administrator transmitted the required notice to place 7-hydroxymitragynine above a specified threshold in schedule I on a temporary basis to the Assistant Secretary for Health of HHS (Assistant Secretary).[9] By letter

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[4] 21 U.S.C. 811(h)(1).
[5] 21 U.S.C. 811(h)(2).
[6] 21 U.S.C. 811(h)(1); 21 CFR part 1308.
[7] 28 CFR 0.100.
[8] 21 U.S.C. 811(h)(4).
[9] 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).

dated March 6, 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 these substances. The Assistant Secretary also stated that HHS had no objection to the temporary placement of this substance above the specified threshold in schedule I of 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 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.[10] This consideration includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of 7-hydroxymitragynine above the specified threshold.[11]

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[12] Substances in schedule I have high potential for abuse, no currently accepted medical use in treatment in the United States,[13] and a lack of accepted safety for use

[10] 21 U.S.C. 811(c)(4)-(6), (h)(3).
[11] 21 U.S.C. 811(h)(3).
[12] 21 U.S.C. 811(h)(1).
[13] 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 7-hydroxymitragynine has 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 7-

under medical supervision.[14]

7-Hydroxymitragynine Above a Specified Threshold

7-Hydroxymitragynine is a psychoactive alkaloid found in *Mitragyna speciosa* (*M. speciosa*) plant, a tropical evergreen tree indigenous to Southeast Asia. While the use of the plant was once geographically limited, the use of *M. speciosa* has since extended to the United States and other global markets. Among the numerous alkaloids identified in *M. speciosa,* the indole alkaloids mitragynine (major) and 7-hydroxymitragynine (minor) are primarily responsible for the plant's psychoactive effects. In its natural botanical form, 7-hydroxymitragynine makes up less than two percent of the total alkaloid content or occurs in trace amount in *M*. *speciosa.* However, 7-hydroxymitragynine can be synthesized from mitragynine through a one-step chemical reaction, and it also exists as an active oxidized metabolite of mitragynine *in vivo*. Despite the different origins of 7-hydroxymitragynine, the chemical structures of synthetic and naturally occurring 7-hydroxymitragynine are identical. Consequently, the intrinsic pharmacological profile, receptor affinity, and mechanism of action of 7-hydroxymitragynine molecule remain unchanged regardless of its source. While consumers of raw plant matrix may experience a modified or attenuated physiological effect due to the competitive, co-occurring alkaloids inherent to *M.speciosa*, isolated or semi-synthetically derived formulations deliver unattenuated, high-potency effects of the target alkaloid directly, representing a distinct public safety profile when concentrated above the proposed threshold.

Recently, the United States has seen a proliferation of 7-hydroxymitragynine products. Evidence suggests that commercially available products, including extracts and synthetic formulations, contain a significantly higher concentration of 7-hydroxymitragynine than what is found in botanical *M. speciosa*. These products are commonly sold on the Internet and in retail

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hydroxymitragynine or that the use of this substance is recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied. In HHS' letter dated March 6, 2026, HHS advised DEA that there were currently no approved NDAs or INDs for these substances. Additionally, HHS noted it had no objections to the temporary placement of this 7-hydroxymitragynine above the specified threshold in schedule I of the CSA.

[14] 21 U.S.C. 812(b)(1).

outlets, such as gas stations and smoke shops, in various forms, including powders, tablets, gummies, and sublingual films designed for rapid absorption. To date, the safety profile of these concentrated products in humans remains unknown because no controlled clinical trials have been conducted to establish safe consumption limits or standardized dosing.

7-Hydroxymitragynine has opioidergic activity, sharing a similar pharmacological profile to schedule II opioids like morphine. Preclinical data[15] indicates that 7-hydroxymitragynine carries a high abuse potential with safety risks, including tolerance, dependence, and respiratory depression, which are comparable to those of classic opioid analgesics. The United States has recently seen an emergence of products containing 7-hydroxymitragynine, which are often characterized by ambiguous dosages and misleading marketing, frequently being labeled as "natural *M. speciosa* extracts." While sellers promote these products for their euphoric and opioidergic effects, evidence demonstrates they may also contain other opioid alkaloids, such as mitragynine pseudoindoxyl. These combinations, coupled with a lack of regulatory oversight, pose significant safety risk to unsuspecting consumers by exposing them to high doses of opioids. The absence of clinical evidence to support vendor health claims is deeply concerning. Consequently, 7-hydroxymitragynine products sold as unregulated dietary supplements pose significant health risks, as essential information regarding their purity, identity, quantity and long-term safety remain unknown.

7-Hydroxymitragynine does not meet the United States Food and Drug Administration (FDA) safety standard for dietary supplements, or dietary ingredients, and it has not been proven safe or effective for any drug use. FDA has issued warning letters to companies clarifying that 7-hydroxymitragyine is not an FDA-approved drug product and no food additive regulation has authorized the use of 7-hydroxymitragynine in food supply. Furthermore, FDA has warned consumers against using products labeled as 7-hydroxymitragynine, as they have not been

[15] Hemby, S. E., McIntosh, S., Leon, F., Cutler, S. J., & McCurdy, C. R. (2019). Abuse liability and therapeutic potential of the Mitragyna speciosa (kratom) alkaloids mitragynine and 7-hydroxymitragynine. *Addiction biology*, *24*(5), 874–885.

proven safe or effective for any use.[16] Fatal overdoses involving 7-hydroxymitragynine have been reported, making its wide availability and unknown safety profile a significant threat to public health, which is particularly concerning in the midst of an opioid crisis. The availability of 7-hydroxymitragynine-containing substances in the United States' *M. speciosa* consumer market poses an imminent hazard to the public safety.

Available data and information for 7-hydroxymitragynine, summarized below, indicate that this substance has 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-1570.

Factor 4. History and Current Pattern of Abuse

7-Hydroxymitragynine is most commonly used in isolated form or as component of *M. speciosa.* Historically, *M. speciosa* has been used for a variety of purposes, including as an opium substitute and a treatment of various opioid withdrawal symptoms, such as pain, cough, anxiety, diarrhea, and intestinal difficulty.[17] While its use was once geographically limited, the marketing in the United States of 7-hydroxymitragynine products has been aggressive and often indistinguishable from the sale of *M. speciosa.*[18] In recent years, 7-hydroxymitragynine has been unlawfully marketed as a dietary supplement[19] or natural extract despite failing to meet FDA's

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[16] FDA Issues Warning Letters to Firms Marketing Products Containing 7-Hydroxymitragynine | FDA, *available at* https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-firms-marketing-products-containing-7hydroxymitragynine#:~:text=FDA%20Issues%20Warning%20Letters%20to%20Firms%20Marketing%20Products%20Containing%207%2DHydroxymitragynine,-Alkaloid%20known%20as&text=The%20U.S.%20Food%20and%20Drug,also%20known%20as%207%2DOH, Accessed July 31, 2025.

[17] Grundmann, O., Green, M., Berthold, E., Yoon, S. L., & Ray, D. (2025). Prevalence and Use Patterns of Kratom (*Mitragyna speciosa* Korth.) in a US Nationally Representative Sample. *Journal of psychoactive drugs*, 1-9.

[18] Smith, K. E., Boyer, E. W., Grundmann, O., McCurdy, C. R., & Sharma, A. (2025). The rise of novel, semi-synthetic 7-hydroxymitragnine products. *Addiction (Abingdon, England)*, 120(2), 387–388.

[19] FDA issued warning letters to firms marketing products containing 7-hydroxymitragynine stating it is not a lawful dietary supplement, food additive, or ingredient in any approved drug". FDA Issues Warning Letters to Firms Marketing Products Containing 7-Hydroxymitragynine | FDA, *available at* https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-firms-marketing-products-containing-7-hydroxymitragynine#:~:text=FDA%20Issues%20Warning%20Letters%20to%20Firms%20Marketing%20Products%20Containing%207%2DHydroxymitragynine,-

safety standard for dietary supplements or dietary ingredients. Anecdotal information from users who post on social media indicates that many users are self-treating chronic pain with unregulated 7-hydroxymitragynine products.[20]

Product Formulation and Marketing Claims

7-Hydroxymitragynine products are readily obtained from smoke shops, gas stations, and online vendors in various forms, including tablets, liquid oral beverages (shots), capsules, powder, syrup, vapes, sublingual pouch/strips, nasal spray, chewable, and liquid extracts. These products are commonly sold with names such as "7 Ohmz," "7-hydroxy,", and "7-OH," and they are presented in colorful packages. One investigation identified 250 products sold between September 2024 through February 2025, noting that chewable/sublingual tablets were the most common formulation.[21] These products were sold for general wellbeing and claims of increased focus. The investigation further highlighted the concerns regarding standardized dosing and cost. The concentration of 7-hydroxymitragynine products varied significantly, ranging from 1 mg to 700 mg in a single dose or serving. The average cost per dose across most products containing 7-hydroxymitragynine was about $3.97.

Anecdotal information synthesized from user-contributed reports and subsequently analyzed by clinical educators[22] between 2024 and early 2025 provide additional information on abuse patterns. Users consistently report transition from traditional kratom leaf to 7-hydroxymitragynine tablets (e.g., 7OHMZ, Press'd, Hydroxie). 7-Hydroxymitragynine was described as "the cleanest and most euphoric high" that lacks "ceiling effect of nausea" of the

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Alkaloid%20known%20as&text=The%20U.S.%20Food%20and%20Drug,also%20known%20as%207%2DOH, accessed on July 15, 2025.

[20] National Drug Early Warning System (NDEWS). (2025). Alert from the NDEWS Web Monitoring Team: Online mentions of Kratom and Derivatives (May 30, 2025). Retrieved from ndews.org

[21] 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.

[22] University of Connecticut School of Pharmacy and Pharmaceutical Sciences. (2025), Kratom and Knock Offs, Should You Leaf Them Alone: You Asked for It!. *available at* https://pharmacy.uconn.edu/course/kratom/

plain leaf. A dominant theme is the short-lived nature of the 7-hydroxymitragynine high. Users report the urge to redose frequently.

The National Drug Early Warning System (NDEWS) conducted web monitoring on reddit mentions of kratom and its derivates. In the report, information provided by reddit discussants surrounding kratom and 7-hydroxymitragynine shows that users often compare 7-hydroxymitragynine effects to prescription opioids, like oxycodone and hydrocodone, with users expressing worry on how such potent products are legally available at smoke shops. Commenters mentioned the ease and convenience of buying products at gas stations and noted how this can be a concern for impulse use due to ease of accessibility. Further, discussions on full commercial retail package prices ranged from $15-40 per retail unit, [23] which is consistent with multi-dose presentation of these commercial formulations.

In summary, 7-hydroxymitragynine products are available in different forms and can be purchased easily via several avenues, predominantly via the Internet. This is a shift from traditional botanical use to aggressive marketing of highly concentrated opioid products in the United States.

Factor 5. Scope, Duration, and Significance of Abuse

The abuse of 7-hydroxymitragynine is increasing and widespread. Given its pharmacological profile as an opioid agonist and high abuse potential,[24] the marketing of 7-hydroxymitragynine products to consumers as botanical supplements constitute a significant public health risk. 7-Hydroxymitragynine, a potent opioid, presents overdose risk and toxicity to users because its chemical manufacturing process is inconsistent and does not adhere to good manufacturing practices. This lack of oversight may lead to variation in doses and composition in final products. Further, 7-hydroxymitragynine is sold as sublingual pouch/tablet, a

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[23] Alert from the NDEWS Web Monitoring Team: Online mentions of Kratom and Derivatives (May 30, 2025). Retrieved from ndews.org.

[24] Hemby, S. E., McIntosh, S., Leon, F., Cutler, S. J., & McCurdy, C. R. (2019). Abuse liability and therapeutic potential of the Mitragyna speciosa (kratom) alkaloids mitragynine and 7-hydroxymitragynine. *Addiction Biology*, 24(5), 874–885.

formulation known to deliver drugs rapidly into the systemic circulation. This rapid delivery, coupled with 7-hydroxymitragynine's known pharmacokinetic profile, contributes to its high potential for abuse.[25]

7-hydroxymitragynine sellers make claims of its opioidergic effects. Evidence demonstrates that 7-hydroxymitragynine products have been identified to contain other opioid alkaloids, such as mitragynine pseudoindoxyl.[26] These combinations and practice pose significant safety risks to unsuspecting consumers by exposing them to high doses of opioids. The lack of evidence to support health claims made by vendors selling 7-hydroxymitragynine products is worrisome. Hence, 7-hydroxymitragynine products sold as dietary supplements pose significant health risks to users because information on their purity, identity, quantity and safety is unknown.

Law Enforcement Encounters

The number of seizures for 7-hydroxymitragynine as reported in law enforcement systems is currently limited, primarily because forensic chemists often prioritize the identification of mitragynine, the major alkaloid in *M. speciosa*, rather than extending analysis to the identification of minor alkaloids, such as 7-hydroxymitragynine. Furthermore, because 7-hydroxymitragynine is not federally controlled under the CSA, specific forensic identification may be limited. Consequently, some forensic laboratories may not place emphasis on analyzing or tracking the encounters of non-controlled substances, making it unlikely to be fully reported to forensic laboratories databases. Nonetheless, available data from the National Forensic Laboratory Information System (NFLIS) database[27] shows that, in 2025, there were 42 reports of

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[25] 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; Sharma, A., Smith, K. E., Kuntz, M. A., Berthold, E. C., Elashkar, O. I., Guadagnoli, N., Kanumuri, S. R. R., Mukhopadhyay, S., Panlilio, L. V., Epstein, D. H., & McCurdy, C. R. (2025). Chemical Analysis and Alkaloid Intake for Kratom Products Available in the United States. *Drug Testing and Analysis*, 17(10), 1974-1984.

[26] 7-Hydroxy Mitragynine NPS Discovery, *available at* https://www.cfsre.org/images/content/reports/public_alerts/7-Hydroxy_Mitragynine_NPS_Discovery_033125.pdf, accessed March 10, 2026.

[27] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes

7-hydroxymitagynine from 12 states. This law enforcement data illustrates the widespread and increasing availability of products containing 7-hydroxymitragynine within the domestic kratom drug market.

FDA Warning Letters

Between June and July 2025, FDA issued seven warning letters[28] to marketers and distributors for the unlawful use of 7-hydroxymitragynine as a drug, dietary supplement, or added to conventional food. The warning letters explicitly stated that 7-hydroxymitragyine is not an FDA-approved drug product and that no food additive regulation has authorized the use of 7-hydroxymitragynine in food. FDA further classified 7-hydroxymitragynine as a "new dietary ingredient" under section 413(d) of the FD&C Act, 21 U.S.C. 350b(d), because there is no evidence demonstrating it was marketed as a dietary ingredient in the United States before October 15, 1994. Additionally, some letters noted that, as a dietary supplement, 7-hydroxymitragynine is considered adulterated under section 402(f)(l)(B) of the FD&C Act,21 U.S.C. 342(f)(l)(B). This is because there is inadequate information providing reasonable assurance that the ingredient does not present a significant or unreasonable risk of illness or injury. Of note was FDA's warning letter issued on June 25, 2025, to a company selling

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data from forensic laboratories that handle more than 96 percent of an estimated 1.0 million distinct annual State and local drug analysis cases. 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 were queried on February 26, 2026.

[28] FDA Issues Warning Letters to Firms Marketing Products Containing 7-Hydroxymitragynine | FDA, *available at* https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-firms-marketing-products-containing-7-hydroxymitragynine ; 7Tabz Retail, LLC - 709546 - 06/25/2025 | FDA, *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/7tabz-retail-llc-709546-06252025; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hydroxie-llc-709661-06252025; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/shaman-botanicals-llc-709622-06252025; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/royal-diamond-imports-inc-709540-06252025; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/thang-botanicals-inc-dba-7ohmz-7-ohmz-or-7ohmz-710190-06252025; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/relax-relief-rejuvenate-trading-llc-dba-rrr-trading-or-edp-kratom-709475-06252025; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/relax-relief-rejuvenate-trading-llc-dba-rrr-trading-or-edp-kratom-709475-06252025.

"7OHMZ 7-Hydroxymitragynine Gummies,"[29] in which FDA cautioned that such products may be appealing to children due to their packaging. Other warning letters targeted the illegal sale of unapproved 7-hydroxymitragynine products marketed for the treatment of pain, relaxation, mood enhancement, and other medical conditions.[30] Vendors utilized websites and social media pages to make unproven medical claims for 7-hydroxymitragynine, such as describing tablets as "expertly formulated to provide a potent dose" or promising "intense relaxation and a feeling of pure bliss."

State Regulations and Controls

Due to concerns over its abuse, several states have regulated or banned the consumption of 7-hydroxymitragynine or *M. speciosa*.[31] Currently, nine states (Alabama, Arkansas, Florida, Indiana, Kentucky, Louisiana, Ohio, Vermont, and Wisconsin) have prohibited 7-hydroxymitragynine consumption. Additionally, some states, such as Arizona, Colorado, South Carolina, and Texas, have set restrictions on the limits of 7-hydroxymitragynine (not to exceed a specified percent of total alkaloid content).

Furthermore, 19 states have enacted model legislation known as the "kratom consumer protection Act (KCPA)," which requires that *M. speciosa*, mitragynine, or 7-hydroxymitragynine be manufactured safely, labeled accurately, and distributed appropriately to protect consumer under a certain age. These states are Arizona, Colorado, Florida, Georgia, Kentucky, Oklahoma, Maryland, Mississippi, Nebraska, Nevada, New York, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, and West Virginia. Other states, like Illinois, New

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[29] Thang Botanicals, Inc. d/b/a 7ΩHMZ, 7-OHMZ, or 7OHMZ - 710190 - 06/25/2025 | FDA, *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/thang-botanicals-inc-dba-7ohmz-7-ohmz-or-7ohmz-710190-06252025.

[30] FDA Warning Letter, Royal Diamond Imports, Inc. (June 25, 2025), *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/royal-diamond-imports-inc-709540-06252025; FDA Warning Letter, Hydroxie, LLC (June 25, 2025), *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hydroxie-llc-709661-06252025.

[31] Legislative Analysis and Public Policy Association, Kratom: Summary of State Laws (April 2025), *available at https://legislativeanalysis.org/wp-content/uploads/2025/07/Kratom-Summary-of-State-Laws.pdf*. Accessed August 8, 2025.

Hampshire, North Carolina, and Tennessee, have bans in some localities.[32] Of note, the state of Mississippi has set the limit per weight basis to one percent of total alkaloid content of 7-hydroxymitragynine or 0.5 mg per container. DEA's intent to temporarily control 7-hydroxymitragynine above the specified threshold does not preempt more restrictive state law regarding the consumption of 7-hydroxymitragynine and 7-hydroxymitragynine-related products.[33]

Poison Control Center Data (National Poison Data System)

The significance of 7-hydroxymitragynine abuse is demonstrated by an increasing volume of calls to poison control centers. Reporting for 7-hydroxymitragynine was historically limited within the National Poison Data System (NPDS); however, specific data codes for this substance were recently implemented between February and May 2025. During the initial tracking period from February 2025 to April 2025, NPDS recorded a total of 53 case reports involving 7-hydroxymitragynine. Of these exposure calls, 37 cases involved single-substance exposure of 7-hydroxymitragynine alone, and 24 cases were classified as abuse involving other substances in combination with 7-hydroxymitragynine. Among the single-substance exposure calls, 16 cases were categorized as intentional abuse, while 13 calls involved moderate medical outcomes where the patients exhibited pronounced and prolonged systemic symptoms.

Expanded data from United States poison centers indicates a rapid escalation in reported incidents.[34] From January 1 through July 31, 2025, there were 165 exposure cases involving 7-hydroxymitragynine. Of those reporting exposures to 7-hydroxymitragynine alone, 35 percent of these cases resulted in serious health problems, and 67 percent of individuals were treated at a healthcare facility. Patients exposed to 7-hydroxymitragynine frequently exhibit a range of severe physiological and neurological symptoms, including: gastrointestinal (nausea and

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[32] American Kratom Association, Kratom State Legality and Legislation, *available at* https://www.americankratom.org/aka-in-your-state. Accessed on February 26, 2026.
[33] *See* 21 U.S.C. 903; 21 CFR 1307.02.
[34] America's Poison Centers, Health Advisory: Serious Illnesses Associated with 7-OH Use, *available at* https://poisoncenters.org/news-alerts/13531044. Accessed on August 26, 2025.

vomiting), neurological (agitation, confusion, loss of consciousness, and seizure), cardiovascular (sweating, tachycardia, and hypertension), and respiratory (difficulty breathing). According to HHS' review, users report several reasons for using 7-hydroxymitragynine, including the following:

- **Desired Effects**: Euphoria and an opioid-like "buzz"/high as motivation for using 7-hydroxymitragynine.
- **Product Appeal**: The availability of "candy-like" formulations of some 7-hydroxymitragynine tablets, which some users acknowledge as carrying health risk due to possibility of overconsumption.
- **Self-Treatment**: Claim of 7-hydroxymitragynine therapeutic value in self-treating pain and anxiety
- **Risk Awareness**: There is an acknowledgement among users of products containing 7-hydroxymitragynine that these products can lead to addiction, withdrawal symptoms, overdose, and other serious health outcomes, including death.

In summary, the abuse of 7-hydroxymitragynine in the United States is fueled by its pharmacological similarities to opioid analgesics, a lack of regulatory controls, and the relative ease of obtaining 7-hydroxymitragynine products via smoke shops and the Internet.[35] Furthermore, the consumption of 7-hydroxymitragynine alongside other mind-altering substances may exacerbate the potential acute and long-term hazards and risks to the user, especially drug dependence. FDA responded to the increase in sales of 7-hydroxymitragynine products and unsubstantiated medical claims by issuing warning letters to companies to protect public safety. Available information from published literatures and poison control centers suggests that 7-hydroxymitragynine is used by a diverse population for the self-treatment of various health conditions. The ingestion of 7-hydroxymitragynine, a potent opioid, alone or co-

[35] Internet sellers advertise, market, and provide false medical claims.

ingestion with other substances, commonly a CNS depressant, is of serious concern. The poison control center data and popularity of 7-hydroxymitragynine-products collectively underscores the severity and significance of abuse of 7-hydroxymitragynine in the United States.

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

7-hydroxymitragynine has opioidergic and addictive properties. Available preclinical data demonstrates that 7-hydroxymitragynine has an abuse potential similar to that of schedule I and II opioids, such as heroin, morphine, and fentanyl.[36] The abuse of 7-hydroxymitragynine presents severe risks to public health, including tolerance, dependence and addiction, respiratory depression, and death. Public health assessment is further complicated because 7-hydroxymitragynine is a known metabolite of mitragynine, making it difficult to distinguish between the ingestion of *M. speciosa* and other isolated 7-hydroxymitragynine products.

FDA-Adverse Event Reporting System (FAERS)

On August 11, 2025, DEA queried the FAERS public dashboard for 7-hydroxymitragynine and noted that there were 1 case count in 2023, 2 cases in 2024, and 11 cases as of June 30, 2025. Most of the cases involved drug dependence (n = 6) and withdrawal syndrome (n = 4). A recent query of the database on February 27, 2026, revealed an increase in cases involving 7-hydroxymitragynine. The total count for 2025 increased to 66 with 17 new cases already reported for 2026. Of the total 86 cases currently within the database, 79 cases were reported as serious, including death. To date, 9 cases within the FAERS database have resulted in death.

DEA Toxicology Testing Program (DEA TOX)

DEA TOX program, which investigates the presence of new psychoactive substances in biological samples from drug overdoses, has identified 7-hydroxymitragynine in 85 cases since

[36] Alsbrook, S., Pro, G., & Koturbash, I. (2025). From kratom to 7-hydroxymitragynine: evolution of a natural remedy into a public-health threat. *Pharmaceutical Biology*, 63(1), 896–911.

2019.[37] Of these, 55 were fatal and 30 were non-fatal cases. These cases involved both males and females with a median age of 36. The average concentration of 7-hydroxymitragynine detected in biological samples was 463.23 ng/mL. Samples often contained other related alkaloids (mitragynine and mitragynine pseudoindoxyl) or other drug classes, such as opioids (e.g. fentanyl), benzodiazepines (e.g. bromazolam), and ketamine. Between 2020 and 2025, there has been a significant increase in the positive identification of 7-hydroxymitragynine in fatal overdose cases.

Case Reports Involving 7-Hydroxymitragynine

In 2025, California,[38] Pennsylvania,[39] and Texas health authorities linked 7-hydroxymitragynine and concentrated extracts to several illness and overdose cases.[40] Other notable cases are summarized in the table below:

7-Hydroxymitragynine Case reports (2014- 2026)

Case Report Author	**Patient Profile**	**Primary Complication**	**Clinical Finding**
Broul et al. (2025)[41]	31 y/o male	Acute Psychosis	Severe Self-Harm: Documented 7-hydroxymitragynine induced psychosis leading to self-amputation (ears/genitalia)

[37] 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. Queried on March 5, 2026.

[38] LISTING OF DEPARTMENT OF PUBLIC HEALTH PRESS RELEASES, *available at* http://publichealth.lacounty.gov/phcommon/public/media/mediapubhpdetail.cfm?prid=5156. October 10, 2025.

[39] Increased Volume of Calls Related to Kratom/Mitragynine and 7-hydroxymitragynine (7-OH) to Pennsylvania's Poison Centers, *available at* https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/2025%20HAN/2025-802-%208-4-%20Kratom.pdf. August 4, 2025

[40] Serious Illnesses Associated with 7-OH Use | Texas DSHS, *available at* https://www.dshs.texas.gov/news-alerts/serious-illnesses-associated-7-oh-use. September 2, 2025.

[41] Broul, M., Rudenko, X., Bajus, A., Král, J., Kyenge, D. M., Staňková, Z., & Albrecht, J. (2025). Case Report: Cannabis and kratom-induced self-amputation of ears and penis. *Frontiers in psychiatry*, *16*, 1479863.

Karinen et al. (2014)[42]	24 y/o male	Fatal Overdose	Fatality: Identified a 7-hydroxymitragynine blood concentration of 0.15 mg/L
Pullman et al. (2026)[43]	29 y/o male	Cardiopulmonary arrest	Naloxone Reversal: Confirmed 7-hydroxymitragynine causes opioid respiratory depression reversible with standard antagonist drug.
Wightman and Hu (2025)[44]	38 y/o male	Severe Dependence	Clinical Detoxification: Patient required inpatient buprenorphine stabilization for high dose 7-hydroxymitragynine withdrawal.

These 7-hydroxymitragynine products are obtained through unknown sources, where the identity, purity, and concentration of active ingredients are often unknown, uncertain, and inconsistent; thus, posing significant adverse health risks to users. The abuse of 7-hydroxymitragynine poses a substantial hazard to public safety. 7-Hydroxymitragynine is being abused for its opioid-like effects and shares health risks similar to other mu-opioid receptor agonists, such as morphine (schedule II). With no approved medical use, the positive identification of 7-hydroxymitragynine in non-fatal and fatal overdose cases poses a threat to public safety. 7-Hydroxymitragynine products are obtained through unknown sources (commonly through the Internet); the identity, purity, and quantity of these substances are uncertain and inconsistent, thus posing significant adverse health risks to users.

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

[42] Karinen R., Posen J.T., Rogde S., & Vindenes V. (2014). An accidental poisoning with mitragynine. *Forensic Science International*, 245, 29-32.
[43] Pullman M.K., Raju Kanumuri S.R., Leon J.F., Cutler S.F., McCurdy C.R., & Sharma. A. (2026). Cardio-pulmonary arrest in a patient revived with naloxone following reported use of 7-hydroxymitragynine. *Clinical Toxicology*, 64(1), 65-66.
[44] Wightman, R. S., & Hu, D. (2025). A Case of 7-OH Mitragynine Use Requiring Inpatient Medically Managed Withdrawal. *Journal of Addiction Medicine*, Aug 4. doi: 10.1097/ADM.0000000000001558. Advance online publication.

summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of 7-hydroxymitragynine pose an imminent hazard to public safety. DEA is not aware of any currently accepted medical uses for 7-hydroxymitragynine in treatment 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 7-hydroxymitragynine indicate that this substance has 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 February 24, 2026, of DEA's intention to temporarily place 7-hydroxymitragynine above a specified threshold in schedule I. In a letter dated March 6, 2026, the Assistant Secretary for Health had no objection to the temporary placement of 7-hydroxymitragynine above the specified threshold in schedule I.

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 7-hydroxymitragynine above a specified threshold in schedule I of the CSA, and finds that placement of this substance above a specified threshold in schedule I of the CSA is necessary in order to avoid an imminent hazard to the public's safety.

The temporary placement of 7-hydroxymitragynine above a specified threshold 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.[45] 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, 7-hydroxymitragynine above a specified threshold 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.[46] The regular scheduling process of formal rulemaking affords 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.[47] Temporary scheduling orders are not subject to judicial review.[48]

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

[45] 21 U.S.C.811(h)(1) and (2).
[46] 21 U.S.C. 811.
[47] 21 U.S.C. 877.
[48] 21 U.S.C. 811(h)(6).

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.[49]

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*."[50] 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.[51] 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 specifically requires the Administrator (as delegated by the Attorney General) to follow rulemaking procedures for *other* kinds of scheduling actions,[52] 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

[49] 21 U.S.C. 811(h)(1).
[50] 5 U.S.C. 551(6) (emphasis added).
[51] 21 U.S.C. 811(a) and 877.
[52] *See* 21 U.S.C. 811(a).

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 Acting Assistant Secretary in response to the notice that DEA transmitted to the Acting 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.[53] 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 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.

[53] 21 U.S.C. 811(h)(1).

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 paragraph (h)(91) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

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(91) Methyl (*E*)2-((2*S*,3*S*,7*aS*)-3-ethyl-7*a*-hydroxy-8-methoxy-1,2,3,4,6,7,7*a*,12*b*-octahydroindolo[2,3-*a*]quinolizin-2-yl)-3-methoxyacrylate (commonly known as 7-hydroxymitragynine; also known as (αE,2*S*,3*S*,7a*S*,12b*S*)-3-ethyl-l,2,3,4,6,7,7a,12b-octahydro-7a-hydroxy-8-methoxy-a-(methoxymethylene)-indolo[2,3-*a*]quinolizine-2-acetic acid, methyl ester) above a specified threshold, described as: (A) *Any botanical material of the plant Mitragyna speciosa, also known as kratom, and contains more than 0.050 percentage of 7-hydroxymitragynine on a dry weight basis, or*	9675

(B) *Any alternative article or material to that described in (A), that is:* i. *Resulting from synthetic methods and containing 7-hydroxymitragynine present in amounts greater than 0.050 percentage weight/weight, weight/volume, or volume/volume or greater than 1.00 milligram of 7-hydroxymitragynine in the article, or* ii. *Material derived from Mitragyna speciosa and further processed to manufacture alternative dosage forms such as extracts, concentrates, processed edibles, or pressed pills, and which may have materials that have been exposed to chemical, thermal, or other methods leading to chemical transformations that result in 7-hydroxymitragynine present in amounts greater than 0.050 percentage weight/weight, weight/volume, or volume/volume or greater than 1.00 milligram of 7-hydroxymitragynine in the article.*	
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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. 2026-13580 Filed: 7/1/2026 4:15 pm; Publication Date: 7/6/2026]