DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1356]

Schedules of Controlled Substances: Placement of MDMB-4en-PINACA in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate (other name: MDMB-4en-PINACA), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes 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 MDMB-4en-PINACA.

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

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION: In this final rule, the Drug Enforcement Administration (DEA) permanently places MDMB-4en-PINACA and its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the Controlled Substances Act (CSA).

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)-(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of Health and Human Services (Secretary),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the CSA and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] In the event that the Secretary did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control.

Pursuant to 21 U.S.C. 811(a)(1) and (2), the Attorney General (as delegated to the Administrator of the DEA pursuant to 28 CFR 0.100) may, by rule, and upon the recommendation of the Secretary, add to such a schedule or transfer between such schedules any drug or other substance, if she finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

Background

The neurochemical effects of MDMB-4en-PINACA occur primarily through cannabinoid receptor systems in the brain. MDMB-4en-PINACA binds to cannabinoid subtype 1 (CB1)

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[1] As discussed in a memorandum of understanding entered into by the FDA and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (Mar. 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[2] 21 U.S.C. 811(d)(3).

receptors, functions as a full agonist, and has a binding affinity and functional activity profile that is similar to that of other schedule I cannabinoids, including Δ9-THC, JWH-018, XLR11, and AKB-48. On June 10, 2021, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND) voted to place MDMB-4en-PINACA in Schedule II of the 1971 Convention during its 64th Session held on April 14, 2021.

As a signatory to this international treaty, the United States is required, by scheduling under the CSA, to place appropriate controls on MDMB-4en-PINACA to meet the minimum requirements of the treaty. Because the procedures in 21 U.S.C. 811(d)(3) and (4) for consultation and issuance of a temporary order, discussed in the above legal authority section, were not followed for MDMB-4en-PINACA, DEA is utilizing the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) to control MDMB-4en-PINACA. Such scheduling would satisfy the United States' international obligations.

To meet the minimum requirements of this treaty and to confront this emerging substance, DEA published an order in the *Federal Register* on December 12, 2023, temporarily placing MDMB-4en-PINACA in schedule I of the CSA based upon a finding that this substance poses an imminent hazard to the public safety under 21 U.S.C. 811(h)(1).[3] That temporary order was effective upon the date of publication. On December 11, 2025, DEA published a temporary scheduling order to extend the temporary schedule I status of MDMB-4en-PINACA for one year, or until the permanent scheduling action for this substance is completed, whichever occurs first.[4]

DEA and HHS Eight-Factor Analyses

In a letter dated September 29, 2023, in accordance with 21 U.S.C. 811(b), and in response to DEA's November 19, 2021 request, the Department of Health and Human Services

[3] *Schedules of Controlled Substances: Temporary Placement of MDMB–4en–PINACA, 4F–MDMB–BUTICA, ADB–4en–PINACA, CUMYL–PEGACLONE, 5F–EDMB–PICA, and MMB–FUBICA into Schedule I*, 88 FR 86040 (Dec. 12, 2023).
[4] *Schedules of Controlled Substances: Extension of Temporary Placement of MDMB-4en-PINACA in Schedule I of the Controlled Substances Act***,** 90 FR 57356 (Dec. 11, 2025).

(HHS) provided to DEA a scientific and medical evaluation and scheduling recommendation for MDMB-4en-PINACA. DEA reviewed the scientific and medical evaluation and scheduling recommendation for schedule I placement provided by HHS, and all other relevant data, pursuant to 21 U.S.C. 811(b) and (c), and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 811(b)(1), that MDMB-4en-PINACA warrants control in schedule I. Both the DEA and HHS's Eight-Factor Analyses are available in their entirety under the tab Supporting Documents of the public docket for this action at https://www.regulations.gov under docket number DEA-1356.

Notice of Proposed Rulemaking To Schedule MDMB-4en-PINACA

On October 2, 2025, DEA published a notice of proposed rulemaking (NPRM) to permanently control MDMB-4en-PINACA in schedule I.[5] Specifically, DEA proposed to add MDMB-4en-PINACA to the list of hallucinogenic substances under 21 CFR 1308.11(d). The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before November 3, 2025. DEA did not receive any requests for a hearing. The NPRM also provided an opportunity for interested persons to submit comments on or before November 3, 2025.

Comments Received

DEA received 50 comments in response to the NPRM for the placement of MDMB-4en-PINACA into schedule I of the CSA. As described in detail below, comments were organized into the following general categories: (1) Support of the rule; (2) Opposition to the rule; (3) Mixed support and opposition to the rule; (4) Request for additional information; (5) Procedural deficiencies; and (6) Responses that were not related to this rulemaking.

Comments in support of the rulemaking: Thirty-seven comments were in support of the rulemaking. Supporting responses commonly noted the severe adverse effects following the

[5] *Schedules of Controlled Substances: Placement of MDMB-4en-PINACA in Schedule I*, 90 FR 47663 (Oct. 2, 2025).

ingestion of MDMB-4en-PINACA, the link to toxicity and deaths reported following its use, the concern about the drugs availability in the community, the access to the drug by children, its high potential for abuse, and the lack of accepted medical use.

DEA Response: DEA appreciates the comments in support of this rulemaking.

Comments in opposition to the rulemaking: Three comments were in opposition to the rulemaking. Two commenters felt that placing MDMB-4en-PINACA in schedule I would inhibit research on this substance. The third commenter only noted their opposition to the rule with no additional detail.

DEA Response: DEA appreciates these comments and would like to provide further clarification regarding the control of MDMB-4en-PINACA. MDMB-4en-PINACA has been placed under international control. To comply with treaty obligations, DEA must place MDMB-4en-PINACA under the most appropriate schedule, taking into consideration all appropriate scientific data. Additionally, as set forth in the NPRM, MDMB-4en-PINACA has no currently accepted medical use in treatment in the United States, nor were there any approved New Drug Applications. Therefore, MDMB-4en-PINACA must be placed in schedule I of the CSA along with other substances which have no currently accepted medical use, lack accepted safety for use under medical supervision, and possess a high potential for abuse. With respect to research for potential medical use, the placement of substances in schedule I of the CSA does not preclude bona fide research on these substances.[6] DEA registrants wishing to conduct research on schedule I substances may apply for permission to do so through the schedule I researcher registration program.[7,8]

Comments showing mixed support and opposition to the rulemaking: Six comments showed mixed support and opposition to the rulemaking. Five of the comments were similar in nature, wherein support was noted due to the serious harmful effects of MDMB-4en-PINACA.

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[6] 21 U.S.C. 823(g)(2)(A).
[7] https://apps.deadiversion.usdoj.gov/webforms2/spring/login?execution=e1s1.
[8] 21 U.S.C. 822(h); 21 U.S.C. 823(g); 21 U.S.C. 823(n).

In opposition, these five comments noted their concern regarding placement of MDMB-4en-PINACA in schedule I could hinder further research. The sixth comment noted that there "was minimum research on MDMB-4en-PINACA to confirm the potential negative effects of its consumption."

DEA Response: As discussed previously, DEA appreciates the comments regarding the serious adverse effects that were described in both the HHS and DEA Eight-Factor Analyses on MDMB-4en-PINACA. DEA noted in the second response above that the placement of MDMB-4en-PINACA in schedule I of the CSA does not preclude bona fide research on this substance. As noted above, a schedule I researcher registration program exists for researchers to continue to conduct research on MDMB-4en-PINACA in compliance with the CSA.[9] The CSA as well as the corresponding regulations provide opportunities for scientific and medical research for all controlled substances while simultaneously mitigating the risk of diversion and potential for public harm.[10] In reference to the sixth comment, DEA notes that research has demonstrated the binding and functional activity of MDMB-4en-PINACA, as well as results from drug discrimination studies. Multiple case reports, including fatal intoxications following the ingestion of MDMB-4en-PINACA, have demonstrated the dangerous effects of this substance, which supports its placement in schedule I of the CSA.

Comment requesting additional information: One commenter requested additional information on why this rulemaking was proposed.

DEA Response: As described within DEA's Eight-Factor Analysis, on June 10, 2021, the Secretary-General of the United Nations advised the Secretary of State of the United States that, during its 64th Session on April 14, 2021, the CND voted to place MDMB-4en-PINACA in Schedule II of the 1971 Convention. As a signatory to this international treaty, the United States is required, by scheduling under the CSA, to place appropriate controls on MDMB-4en-PINACA

[9] https://apps.deadiversion.usdoj.gov/webforms2/spring/login?execution=e1s1.
[10] 21 U.S.C. 822(h); 21 U.S.C. 823(g); 21 U.S.C. 823(n).

to meet the minimum requirements of the treaty. In addition, this substance has shown to be a threat to public health and safety due to the serious adverse effects and fatalities described within the supporting material. For these reasons, MDMB-4en-PINACA was placed in schedule I of the CSA.

Comment raising procedural requests: One comment was received from a public advocacy group with an accompanying attachment, which raised four primary issues and made several requests. First, the commenter claimed that DEA "did not identify or estimate the number of small entities directly regulated, describe the compliance requirements for those entities, or explain why the impacts are not significant," and requested that DEA either (1) withdraw its Regulatory Flexibility Act (RFA) certification and publish an Initial Regulatory Flexibility Analysis, or (2) "reopen the record for 30 days" to receive small-entity impact data and consider reasonable accommodations. Second, the commenter claims that any invocation of good cause under 5 U.S.C. 553(d)(3) "to waive the 30-day delayed effective date" is "inadequate" because "[t]he timing of permanent scheduling is foreseeable" and "avoiding a gap after a temporary order expires is not good cause where the agency had ample time to plan." Third, the commenter stated, in reference to the Paperwork Reduction Act and Executive Order (E.O.) 12866, that "DEA should confirm in the record that this rule does not create any new information collection requirements and identify the relevant Office of Management and Budget (OMB) control numbers that will cover compliance activities related to MDMB-4en-PINACA." Lastly, the commenter requested that "DEA should clarify in the docket its E.O. 12866 significance determination and whether OIRA reviewed the action." [11]

DEA Response: Regarding the first issue, DEA certified in the NPRM that the proposed rule would not have a significant economic impact on a substantial number of small entities and provided the factual basis for that certification. To begin, DEA identified the types of entities

[11] The attachment to the comment that DEA received included the acronym "OIRA" with no further explanation or discussion. DEA assumes that the commenter meant to reference the Office of Information and Regulatory Affairs, which is within OMB.

that would be affected by the proposed rule and determined the North American Industry Classification System industries that best represent those business activities. To determine whether a substantial number of small entities are affected in any of the industries, DEA also relied on data from the Statistics of U.S. Businesses to determine the number of firms and small firms for each of the affected industries, and it then compared the number of affected small entities to the number of small entities for each industry. Further, based on the American Chemical Society's SciFinder database, DEA identified one entity supplying MDMB-4en-PINACA across the relevant industries, and that entity was already registered with DEA to handle controlled substances. Finally, because MDMB-4en-PINACA is not approved for medical use and has a substantial capability to be a hazard to the health of the user and to the safety of the community, DEA expected that the number of researchers working with MDMB-4en-PINACA would be small, and that the researchers working with MDMB-4en-PINACA may also work with other controlled substances; therefore, researchers are likely already registered with DEA and are qualified to handle controlled substances.[12]

Regarding the second issue, DEA finds that there is good cause under 5 U.S.C. 553(d)(3) for this scheduling action to be immediately effective upon publication because a delay in the effective date is unnecessary and contrary to the public interest. The reasons in support of DEA's good-cause finding are set forth below.

Regarding the third issue, DEA stated in the NPRM that the "proposed rule would not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995," and that the "proposed rule would not impose new or modify existing recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations."[13] Because any collection of information requirements have been in place since the DEA temporarily scheduled MDMB-4en-PINACA, and the permanent scheduling of

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[12] *See Schedules of Controlled Substances: Placement of MDMB-4en-PINACA in Schedule I*, 90 FR 47663, 47668-47669 (Oct. 2, 2025).
[13] *Id.* at 47669.

MDMB-4en-PINACA does not create any additional collection requirements, DEA asserts that its statement regarding information collection in the NPRM is supported. DEA also stated in the NPRM that the proposed rule would require compliance with the following existing OMB collections: 1117-0003, 1117-0004, 1117-0006, 1117-0008, 1117-0009, 1117-0010, 1117-0012, 1117-0014, 1117-0021, 1117-0023, 1117-0029, and 1117-0056.[14] Like the NPRM, this final rule provides that same below.

Finally, regarding the fourth issue, section 3(d) of E.O. 12866 provides the definition of a "regulation" or "rule" subject to E.O. 12866. As DEA stated in the NPRM, such actions are exempt from E.O. 12866 pursuant to section 3(d)(1) of E.O. 12866 because a proposed scheduling action under 21 U.S.C. 811(a) is subject to formal rulemaking procedures done "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557.

Comments that were not related to this rulemaking: DEA received two comments that were neither explicitly for nor against the proposed rule. These two comments were not related to the current scheduling action. The first comment discussed oxycodone, while the second comment discussed marijuana.

DEA Response: These comments were outside the scope of the current scheduling action; therefore, these comments were not considered.

Scheduling Conclusion

After consideration of the public comment, scientific and medical evaluation and accompanying scheduling recommendation from HHS, and after its own eight-factor evaluation, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of MDMB-4en-PINACA. As such, DEA is permanently scheduling MDMB-4en-PINACA as a controlled substance under schedule I of the CSA. The permanent scheduling of MDMB-4en-PINACA fulfills the United States' obligations as a party to the 1971 Convention.

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[14] *Id.*

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, II, IV, and V. The CSA also specifies the findings requires to place a drug or other substance in any particular schedule, 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the then Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) MDMB-4en-PINACA has a high potential for abuse that is comparable to other scheduled synthetic cannabinoids, such as JWH-018, XLR11, and ABKB-48. In vitro studies demonstrate that MDMB-4en-PINACA binds to CB1 receptors and functions as a full agonist. In drug discrimination studies conducted in animals to evaluate its discriminative stimulus effects, MDMB-4en-PINACA was shown to fully substitute for the discriminative stimulus effects produced by delta 9-THC. In addition to the large numbers of law enforcement seizures of MDMB-4en-PINACA in various forms including as a powder, on plant material or in vaping devices, the ingestion of MDMB-4en-PINACA has been documented to result in serious adverse effects including agitation, psychosis including hallucinations and delusions, behavioral changes, seizures, brain injury, and death.

(2) MDMB-4en-PINACA has no currently accepted medical use in treatment in the United States. In HHS's 2023 recommendation to control MDMB-4en-PINACA, it was noted there are no approved New Drug Applications for MDMB-4en-PINACA and no known therapeutic applications for MDMB-4en-PINACA in the United States. DEA is not aware of any other evidence suggesting that MDMB-4en-PINACA has a currently accepted medical use in treatment in the United States.[15]

[15] To place a drug or other substance in schedule I under the CSA, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. 21 U.S.C. 812(b)(1)(B). 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 a drug or substance that has not been approved by the FDA: (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. *See Marijuana Scheduling Petition; Denial of Petition; Remand*, 57 FR 10499 (Mar. 26, 1992),

(3) There is a lack of accepted safety for use of MDMB-4en-PINACA under medical supervision. Because MDMB-4en-PINACA has no approved medical use and has not been investigated as a new drug, its safety for use under medical supervision has not been determined.

Based on these findings, the Administrator of DEA concludes that MDMB-4en-PINACA, as well as its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrants control in schedule I of the CSA.

Requirements for Handling MDMB-4en-PINACA

MDMB-4en-PINACA is subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, conduct instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. Registration. Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, MDMB-4en-PINACA must register with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity in a manner not authorized by the CSA is unlawful and those in possession of any quantity may be subject to prosecution pursuant to the CSA.

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pet. for rev. denied, *Alliance for Cannabis Therapeutics v. Drug Enforcement Admin*., 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter 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 practitioners 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 final rule, there is no evidence that health care providers have widespread experience with medical use of MDMB-4en-PINACA, or that the use of MDMB-4en-PINACA is recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied.

2. Disposal of stocks. Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held MDMB-4en-PINACA to a person registered with DEA before the effective date of the final scheduling action in accordance with all applicable Federal, State, local, and Tribal laws. MDMB-4en-PINACA must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and Tribal laws

3. Security. MDMB-4en-PINACA is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling MDMB-4en-PINACA must comply with the employee screening requirements of 21 CFR 1301.90 through 1301.93.

4. Labeling and Packaging. All labels, labeling, and packaging for commercial containers of MDMB-4en-PINACA must comply with 21 U.S.C. 825 and be in accordance with 21 CFR part 1302.

5. Quota. Generally, only registered manufacturers are permitted to manufacture MDMB-4en-PINACA in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

6. Inventory. Every DEA registrant who possesses any quantity of MDMB-4en-PINACA must take an inventory of MDMB-4en-PINACA on hand, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including MDMB-4en-PINACA) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including MDMB-4en-PINACA) on hand every two years, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. Records and Reports. Every DEA registrant must maintain records and submit reports for MDMB-4en-PINACA, or products containing MDMB-4en-PINACA, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and parts 1304, 1312 and 1317. Manufacturers and distributors must submit reports regarding MDMB-4en-PINACA to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. Order Forms. Every DEA registrant who distributes MDMB-4en-PINACA must comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

9. Importation and Exportation. All importation and exportation of MDMB-4en-PINACA must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR parts 1304 and 1312.

10. Liability. Any activity involving MDMB-4en-PINACA not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, 14192, and 14294

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the OMB pursuant to section 3(d)(1) of E.O. 12866 and the principles reaffirmed in E.O. 13563. DEA scheduling actions are not subject to either E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Overcriminalization in Federal Regulations.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal

standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does 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.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have Tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Paperwork Reduction Act of 1995

This action does not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995.[16] Also, this rule does not impose new or modify existing recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. However, this rule would require compliance with the following existing OMB collections: 1117-0003, 1117-0004, 1117-0006, 1117-0008, 1117-0009, 1117-0010, 1117-0012, 1117-0014, 1117-0021, 1117-0023, 1117-0029, and 1117-0056. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Regulatory Flexibility Act

The Administrator of DEA, in accordance with the RFA, 5 U.S.C. 601–612, has reviewed this final rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

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[16] 44 U.S.C. 3501–3521.

DEA is placing the substance MDMB-4en-PINACA (chemical name: methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate), including its salts, isomers, and salts of isomers, in schedule I of the CSA to enable the United States to meet its obligations under the 1971 Convention. This action imposes 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 MDMB-4en-PINACA.

Based on the review of HHS's scientific and medical evaluation and all other relevant data, DEA determined that MDMB-4en-PINACA has high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. There appear to be no legitimate sources for MDMB-4en-PINACA as a marketed drug in the United States, but DEA notes that this substance is available for purchase from legitimate suppliers for scientific research. There is no evidence of significant diversion of MDMB-4en-PINACA from legitimate suppliers. Therefore, this final rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532*,* DEA has determined that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year…." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However,

pursuant to the CRA, DEA is submitting a copy of this rule to both Houses of Congress and to the Comptroller General.

Determination To Make Rule Effective Immediately

The Administrative Procedure Act (APA) generally requires that rules enacted in accordance with the procedures of 5 U.S.C. 553 to be effective not less than 30 days after publication of the proposed rule. 5 U.S.C. 553(d). However, the APA provides three exceptions for when an agency may make a rule effective sooner than 30 days after publication, including if the agency finds for good cause why the rule should be effective sooner and publishes those reasons with the rule. 5 U.S.C. 553(d)(3).

DEA finds that there is good cause for this scheduling action to be immediately effective upon publication because a delay in the effective date is unnecessary and contrary to the public interest. First, it is unnecessary because MDMB-4en-PINACA is currently listed in schedule I of the CSA under 21 U.S.C. 811(h).[17] Second, as discussed in the temporary scheduling order and NPRM, MDMB-4en-PINACA poses imminent hazard to public safety. Therefore, DEA believes it is unnecessary and contrary to the public interest to delay the effectiveness of this final rule by 30 days.[18]

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 amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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[17] *Schedules of Controlled Substances: Temporary Placement of MDMB-4en-PINACA, 4F-MDMB-BUTICA, ADB-4en-PINACA, CUMYL-PEGACLONE, 5F-EDMB-PICA, and MMB-FUBICA into Schedule I*, 88 FR 86040 (Dec. 12, 2023); *Schedules of Controlled Substances: Extension of Temporary Placement of MDMB-4en-PINACA in Schedule I of the Controlled Substances Act*, 90 FR 57356 (Dec. 11, 2025).

[18] *See, e.g.*, *Schedules of Controlled Substances: Placement of beta-Hydroxythiofentanyl in Schedule I*, 84 FR 20023, 20027 (May 8, 2019); *Schedules of Controlled Substances: Placement of UR-144, XLR11, and AKB48 into Schedule I*, 81 FR 29142, 29144 (May 11, 2016); *accord Schedules of Controlled Substances: Placement of Seven Specific Fentanyl-Related Substances in Schedule I*, 90 FR 44979 (Sept. 18, 2025); *Schedules of Controlled Substances: Placement of Nine Specific Fentanyl-Related Substances in Schedule I*, 88 FR 85104 (Dec. 7, 2023).

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:

a. Addparagraph (d)(110); and

b. Remove and reserve paragraph (h)(62).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

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(110) methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate (other name: MDMB-4en-PINACA)	7090
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SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on April 20, 2026, by Assistant Administrator Cheri Oz. 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.

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