Federal Home Loan Bank System Boards of Directors and Executive Management (RIN 2590–AB24)

On November 4, 2024, FHFA published a proposed rule (*see* 89 FR 87730) that would have amended FHFA's regulations on Responsibilities of Boards of Directors, Corporate Practices, and Corporate Governance, Federal Home Loan Bank Directors, and the Office of Finance to address a number of corporate governance-related issues. Primarily, the proposed rule would have updated and clarified regulatory requirements on: (1) FHFA's annual designation of Federal Home Loan Bank directorships; (2) Federal Home Loan Bank director eligibility and professional qualifications; (3) nomination, election, and removal of Federal Home Loan Bank directors; (4) the conduct of Federal Home Loan Bank System board and committee meetings; (5) Federal Home Loan Bank director compensation; (6) Federal Home Loan Bank employee conflicts of interest; and (7) the respective responsibilities of Federal Home Loan Bank System boards of directors and executive management.

Federal Home Loan Bank Unsecured Credit Limits (RIN 2590–AB41)

On October 3, 2024, FHFA published a proposed rule (*see* 89 FR 80422) that would have amended the provision of FHFA's regulation on Federal Home Loan Bank Capital Requirements establishing limits on unsecured extensions of credit to modify limits on Federal Home Loan Bank extensions of unsecured credit in their on- and off-balance sheet and derivative transactions. Currently, overnight federal funds are excluded from the more restrictive ''general limit'' on unsecured credit to a single counterparty and are limited only by the higher ''overall limit.'' The proposed rule would have added interest bearing deposit accounts and other authorized overnight investments to that exclusion, which may have provided greater flexibility and improved cost to yield than overnight federal funds.

Withdrawal of Proposed Rules

FHFA is withdrawing these notices of proposed rulemaking because, as noted above, it no longer intends to issue final rules with respect to these proposals. If FHFA decides to pursue future regulatory action in any of these areas, it will do so by publishing a new proposed rule or other issuance consistent with the requirements of the Administrative Procedure Act, as applicable.

Clinton Jones,

General Counsel, Federal Housing Finance Agency.

[FR Doc. 2025–19429 Filed 10–1–25; 8:45 am]

BILLING CODE 8070–01–P

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: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing 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. If finalized, this action would make permanent the existing regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle MDMB-4en-PINACA.

DATES: Comments must be submitted electronically or postmarked on or before November 3, 2025.

Interested persons may file a request for a hearing or waiver of an opportunity for a hearing or to participate in a hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.47 and 1316.49, as applicable, which must be received or postmarked on or before November 3, 2025.

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference ''Docket No. DEA–1356'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages commenters to submit comments electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your comment submission, you will receive a Comment Tracking Number for your comment. If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.
- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.
- *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be filed with the DEA Administrator, who will make the determination of whether a hearing will be needed to address such matters of fact and law in the rulemaking. Such requests must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. For informational purposes, a courtesy copy of requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

As required by 5 U.S.C. 553(b)(4), a summary of this proposed rule may be

found in the docket for this rulemaking at *www.regulations.gov.*

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) intends to place 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 (CSA).

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. DEA will make comments available for public inspection online at *http://www.regulations.gov,* unless reasonable cause is given. Such information includes personal or business identifiers (such as name, address, state of federal identifiers, etc.) voluntarily submitted by the commenter.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked ''CONTAINS CONFIDENTIAL INFORMATION'' and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked ''TO BE PUBLICLY POSTED'' and must have all claimed confidential PII and business information already redacted. DEA will post only the redacted comment on *https://www.regulations.gov* for public inspection. DEA generally will not redact additional information contained in the comment marked ''TO BE PUBLICLY POSTED.'' The Freedom of Information Act applies to all comments received.

For easy reference, an electronic copy of this document and supplemental information to this proposed scheduling action are available at *http://www.regulations.gov.*

Request for Hearing or Waiver of Participation in a Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559.[1] Interested persons, as defined in 21 CFR 1300.01(b), may file requests for a hearing in conformity with the requirements of 21 CFR 1308.44(a) and 1316.47(a), and such requests must:

(1) state with particularity the interest of the person in the proceeding;

(2) state with particularity the objections or issues concerning which the person desires to be heard; and

(3) state briefly the position of the person regarding the objections or issues.

Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(c), together with a written statement of position on the matters of fact and law involved in any hearing.[2]

All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above. The decision whether a hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the proposed rulemaking in the **Federal Register**.[3] Further, once the Administrator determines a hearing is needed to address such matters of fact and law in rulemaking, he will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ's functions shall commence upon designation, as provided in 21 CFR 1316.52.

In accordance with 21 U.S.C. 811 and 812, the purpose of a hearing would be to determine whether MDMB-4en-PINACA meets the statutory criteria for placement in schedule I, as proposed in this proposed rule.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on her own motion, at the request of the Secretary of Health and Human Services (HHS), or on the petition of an interested party.[4] This proposed action is initiated on the Administrator's own motion and supported by, *inter alia,* a recommendation from the then-Assistant Secretary for Health of HHS.

In addition, 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 HHS (Secretary),[5] 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.[6]

In the event that the Secretary did not 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 are 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 DEA) 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

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

[1] 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D.

[2] 21 CFR 1316.49.

[3] 21 CFR 1308.44(b), 1316.53.

[4] 21 U.S.C. 811(a).

[5] 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).

[6] 21 U.S.C. 811(d)(3).

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.

Article 2, paragraph 7(b), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule II of the 1971 Convention. Pursuant to the 1971 Convention, the United States must require licenses for the manufacture, export and import, and distribution of MDMB-4en-PINACA. This license requirement is accomplished by the CSA's registration requirement as set forth in 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

In addition, the United States must adhere to specific export and import provisions set forth in the 1971 Convention. This requirement is accomplished by the CSA with the export and import provisions established in 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312. Likewise, under Article 13, paragraphs 1 and 2, of the 1971 Convention, a party to the 1971 Convention may notify through the UN Secretary-General another party that it prohibits the importation of a substance in Schedule II, III, or IV of the 1971 Convention. If such notice is presented to the United States, the United States shall take measures to ensure that the named substance is not exported to the notifying country. This requirement is also accomplished by the CSA's export provisions mentioned above.

Under Article 16, paragraph 4, of the 1971 Convention, the United States is required to provide annual statistical reports to the International Narcotics Control Board (INCB). Using INCB Form P, the United States shall provide the following information: (1) In regard to each substance in Schedule I and II of the 1971 Convention, quantities manufactured, exported to, and imported from each country or region as well as stocks held by manufacturers; (2) in regard to each substance in Schedule III and IV of the 1971 Convention, quantities manufactured, as well as quantities exported and imported; (3) in regard to each substance in Schedule II and III of the 1971 Convention, quantities used in the manufacture of exempt preparations; and (4) in regard to each substance in Schedule II–IV of the 1971 Convention, quantities used for the manufacture of non-psychotropic substances or products.

Lastly, under Article 2 of the 1971 Convention, the United States must adopt measures in accordance with Article 22 to address violations of any statutes or regulations that are adopted pursuant to its obligations under the 1971 Convention. Persons acting outside the legal framework established by the CSA are subject to administrative, civil, and/or criminal action; therefore, the United States complies with this provision.

DEA notes that there are differences between the schedules of substances in the 1971 Convention and the CSA. The CSA has five schedules (schedules I–V) with specific criteria set forth for each schedule. Schedule I is the only possible schedule in which a drug or other substance may be placed if it has high potential for abuse and no currently accepted medical use in treatment in the United States.[7] In contrast, the 1971 Convention has four schedules (Schedules I–IV) but does not have specific criteria for each schedule. The 1971 Convention simply defines its four schedules, in Article 1, to mean the correspondingly numbered lists of psychotropic substances annexed to the Convention and altered in accordance with Article 2.

Proposed Determination to Schedule MDMB-4en-PINACA

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on MDMB-4en-PINACA and, on November 29, 2021, submitted it to the then-Assistant Secretary of Health of HHS with a request for a scientific and medical evaluation and scheduling recommendation for this substance. On September 29, 2023, HHS[8] provided DEA with a scientific and medical evaluation entitled ''Basis for the Recommendation to Control MDMB-4en-PINACA and Its Salts in Schedule I of the Controlled Substances Act'' and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b), following consideration of the eight-factors and findings related to the substance's abuse potential, legitimate medical use, and safety or dependence liability, HHS recommended that MDMB-4en-PINACA, its salts, isomers, and salts of isomers be controlled in schedule I of the CSA.[9] HHS noted that MDMB-4en-PINACA is a full agonist at the cannabinoid type 1 (CB1) receptor, has no known medical use in the United States, has no approved new drug applications, and is not known to be marketed anywhere in the world as an approved drug product. HHS also noted that health care practitioners and medical examiners have reported cases of severe clinical adverse events and even death when MDMB-4en-PINACA was used.

On December 12, 2023, the previous Administrator published a temporary scheduling order in the **Federal Register**[10] temporarily placing six synthetic cannabinoids (SCs) in schedule I of the CSA upon finding that these substances pose an imminent threat to public safety. The six SCs temporarily controlled under the CSA were (1) MDMB-4en-PINACA; (2) methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other name: 4F-MDMB-BUTICA); (3) 4F-MDMB-BICA); *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamide (other name: ADB-4en-PINACA); (4) 5-pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one (other names: CUMYL-PEGACLONE; SGT-151); (5) ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 5F-EDMB-PICA; 5F-EDMB-2201); and (6) methyl 2-(1-(4-fluorobenzyl)-1*H*-indole-3-carboxamido)-3-methyl butanoate (other name: MMB-FUBICA). These six SCs have not been investigated for medical use nor are they intended for human use.

As noted above, the Administrator, on his own motion, is now initiating proceedings under 21 U.S.C. 811(a)(1) to permanently schedule MDMB-4en-PINACA in schedule I of the CSA. Upon receipt of the scientific and medical evaluation and scheduling recommendation from HHS, DEA reviewed the documents and all other relevant data and conducted its own eight-factor analysis in accordance with 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its proposed scheduling action. Readers should refer to the full eight-factor analyses prepared by HHS and by DEA in support of this proposal, which are available in their entirety under the tab ''Supporting

[7] *See* 21 U.S.C. 812(b).

[8] Administrative responsibilities for evaluating a substance for control under the CSA are performed for HHS by FDA, with the concurrence of the National Institute on Drug Abuse (NIDA), according to a Memorandum of Understanding. 50 FR 9518 (Mar. 8, 1985).

[9] NIDA concurred with HHS's recommendation.

[10] 88 FR 86040.

Documents'' of the public docket of this rulemaking action at *https://www.regulations.gov,* under docket number ''DEA–1356.''

1. The Drug's Actual or Relative Potential for Abuse

In addition to considering the information HHS provided in its scientific and medical evaluation document for MDMB-4en-PINACA, DEA also considered all other relevant data regarding actual or relative potential for abuse of MDMB-4en-PINACA. The term ''abuse'' is not defined in the CSA; however, the legislative history of the CSA suggests that DEA consider the following criteria in determining whether a particular drug or substance has a potential for abuse: [11]

(a) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

(b) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(c) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(d) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

In its recommendation, HHS noted that the abuse of MDMB-4en-PINACA is creating a hazard to the health and safety of both the individual users and others within the community. According to HHS, MDMB-4en-PINACA has been associated with numerous reports of emergency department admission, severe intoxication, and death. HHS also noted that MDMB-4en-PINACA is not an FDA-approved drug product, MDMB-4en-PINACA is not approved as a drug in any country, and there is no legitimate source for MDMB-4en-PINACA as a marketed drug. Since 2019, the National Forensic Laboratory Information System (NFLIS)-Drug [12] registered 14,801 reports pertaining to MDMB-4en-PINACA. These encounters of MDMB-4en-PINACA by law enforcement indicate that this substance is being trafficked in the United States.[13]

According to HHS, because MDMB-4en-PINACA is not approved for medical use, reports of human self-administration indicate that individuals are taking this substance of their own accord as opposed to under the direction of a medical professional. HHS also stated that the pharmacological action of MDMB-4en-PINACA is similar to other schedule I cannabinoids, such as Δ9-tetrahydrocannabinol (Δ9-THC), which all have high abuse potential. HHS concluded that MDMB-4en-PINACA has a substantial capability to be a hazard to the health of the user and to the safety of the community.

2. Scientific Evidence of the Drug's Pharmacological Effects, if Known

In its recommendation, HHS stated that the neurochemical effects of MDMB-4en-PINACA occur primarily through cannabinoid receptor systems in the brain. HHS noted that MDMB-4en-PINACA binds to CB1 receptors and functions as a full agonist, and that the binding affinity and functional activity profile is similar to that of other schedule I cannabinoids, including Δ9-THC. Studies were conducted to evaluate *in vitro* cannabinoid receptor binding and functional effects of MDMB-4en-PINACA. These results indicate that MDMB-4en-PINACA, similar to other schedule I SCs, binds to CB1 receptors and acts as an agonist at CB1 receptors. Drug discrimination studies were conducted in animals to evaluate whether MDMB-4en-PINACA has discriminative stimulus effects similar to those of other substances in schedule I of the CSA. MDMB-4en-PINACA was shown to fully substitute for the discriminative stimulus effects produced by Δ9-THC.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

MDMB-4en-PINACA is a potent cannabinoid that is reported to be smoked for recreational purposes. MDMB-4en-PINACA is a CB1 receptor agonist that is pharmacologically similar to Δ9-THC. Neither HHS nor DEA is aware of any currently accepted medical use for MDMB-4en-PINACA in treatment in the United States.[14]

4. Its History and Current Pattern of Abuse

HHS reviewed the current literature and law enforcement data supplied by DEA within HHS's recommendation for control of MDMB-4en-PINACA. HHS stated that, although law enforcement data are not direct evidence of abuse, it can be inferred that MDMB-4en-PINACA, like other SCs, has been consumed for the substance's psychoactive and intoxicating effects. HHS also noted that in terms of the propensity of new SCs to emerge as new drugs of abuse, MDMB-4en-PINACA fits an established pattern. MDMB-4en-PINACA was reported in Slovenia in 2018 but didn't appear in the United States until January 2019. Presentations at emergency departments that were directly linked to the abuse of MDMB-4en-PINACA have included violent seizures, body spams, agitation,

[11] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

[12] NFLIS-Drug is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. NFLIS-Drug data were queried February 1, 2024.

[13] While law enforcement data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332 (Dec. 12, 2011).

[14] 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). There is no evidence suggesting that MDMB-4en-PINACA has a currently accepted medical use in treatment in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug or substance that has not been approved by the FDA: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. See *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 and HHS applied the traditional five-part test for currently accepted medical use in this matter. 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 proposal, 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 under either the traditional five-part test or the two-part test.

vomiting, tachycardia, and elevated blood pressure.

5. The Scope, Duration, and Significance of Abuse

According to HHS, SCs continue to be encountered in the illicit market despite scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances. Novel SCs continue to be encountered that differ only by small chemical structural modifications, intended to avoid prosecution while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products. Since 2019, NFLIS registered 20,620 reports pertaining to MDMB-4en-PINACA.

6. What, If Any, Risk There is to the Public Health

HHS and DEA documented multiple cases where MDMB-4en-PINCA was identified in overdoses and/or cases involving death attributed to its abuse in the United States and abroad. Full details of the overdose cases can be found under the tab ''Supporting Documents'' of the public docket of this action at *https://www.regulations.gov,* under Docket Number ''DEA–1356.'' Emergency medical intervention has been required, alongside reports of serious adverse health effects, from these incidents involving MDMB-4en-PINACA.

7. Its Psychic or Physiological Dependence Liability

There are no clinical studies evaluating dependence liabilities specific to MDMB-4en-PINACA. However, scientific data indicate that MDMB-4en-PINACA has a pharmacological profile that is similar to other schedule I SCs. HHS stated that based upon this similar pharmacological profile, it is reasonable to assume that MDMB-4en-PINACA would retain a physiological and psychological dependence liability that is similar to that of Δ9-THC (a schedule I drug) and other schedule I SCs, such as 1-pentyl-3-(1-naphthoyl)indole (JWH–018), [1-(5-fluoropentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB–48).

8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA

As noted by HHS, MDMB-4en-PINACA is not an immediate precursor of any substance controlled under the CSA, as defined by 21 U.S.C. 802(23).

Conclusion

After considering the scientific and medical evaluation conducted by HHS, HHS's scheduling recommendation, and DEA's own eight-factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of MDMB-4en-PINACA. As such, DEA hereby proposes to permanently schedule MDMB-4en-PINACA as a schedule I controlled substance under the CSA. This action would enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule.[15] After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. MDMB-4en-PINACA has a high potential for abuse that is comparable to other schedule I substances such as Δ9–THC and JWH-018;

2. MDMB-4en-PINACA has no currently accepted medical use in treatment in the United States; and

3. There is a lack of accepted safety for use of MDMB-4en-PINACA under medical supervision.

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

Requirements for Handling MDMB-4en-PINACA

If this proposed rule is finalized as proposed, MDMB-4en-PINACA would continue [16] to be 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 of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. Registration. Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) MDMB-4en-PINACA must be registered 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.

2. Security. MDMB-4en-PINACA is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71 through 1301.76. Non-practitioners handling these three substances also must comply with the screening requirements of 21 CFR 1301.90 through 1301.93.

3. Labeling and Packaging. All labels and labeling for commercial containers of MDMB-4en-PINACA must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302.

4. Quota. Only registered manufacturers would be 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.

5. Inventory. Any person registered with DEA to handle MDMB-4en-PINACA must have an initial inventory of all stocks of controlled substances (including this substance) 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.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including MDMB-4en-PINACA) on hand every two years pursuant to 21 U.S.C. 827 and 958(e) and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. Records and Reports. Every DEA registrant must maintain records and submit reports with respect to MDMB-4en-PINACA, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and 1301.76(b) and parts 1304, 1312, and 1317. Manufacturers and distributors would be required to submit reports regarding MDMB-4en-PINACA to the Automation of Reports and Consolidated Order System pursuant 21 U.S.C. 827, and in accordance with 21 CFR parts 1304 and 1312.

7. Order Forms. Every DEA registrant who distributes MDMB-4en-PINACA must comply with the order form

[15] 21 U.S.C. 812(b).

[16] MDMB-4en-PINACA is currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). *See* 88 FR 86040 (Dec. 12, 2023).

requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

8. Importation and Exportation. All importation and exportation of MDMB-4en-PINACA must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

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

Regulatory Analyses

Executive Orders 12866, 13563, 14192 and 14294 (Regulatory Review)

In accordance with 21 U.S.C. 811(a), this proposed scheduling action 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. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (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, Fighting Overcriminalization in Federal Regulations.

Executive Order 12988, Civil Justice Reform

This proposed 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 proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed 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.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this proposed rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. DEA proposes placing the substance 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, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If finalized, this action would 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, MDMB-4en-PINACA.

The entities affected by this proposed rule include the manufacturers, distributors, importers, exporters, and researchers of MDMB-4en-PINACA. DEA determines the North American Industry Classification System (NAICS) industries that best represent these business activities. Table 1 lists the business activities and corresponding NAICS industries.[17]

TABLE 1—BUSINESS ACTIVITY AND CORRESPONDING NAICS INDUSTRIES

Business activity	NAICS code	NAICS industry description
Manufacturer	325412	Pharmaceutical Preparation Manufacturing.
Distributor, Importer, Exporter	424210	Drugs and Druggists' Sundries Merchant Wholesalers.
	424690	Other Chemical and Allied Products Merchant Wholesalers.
Researcher	541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).
	611310	Colleges, Universities and Professional Schools.

From Statistics of U.S. Businesses (SUSB) data, DEA determined the number of firms and small firms for each of the affected industries, and by comparing the number of affected small entities to the number of small entities for each industry, DEA determined whether a substantial number of small entities are affected in any of the industries. Table 2 lists the number of firms, small firms, and percent small firms in each affected industry.

TABLE 2—PERCENT AFFECTED SMALL ENTITIES BY INDUSTRY

NAICS industry	Firms[18]	SBA size standard[19]	Small firms[20]	Percent small entities (%)
325412—Pharmaceutical Preparation Manufacturing	1,179	1,300 employees	1,099	93.2
424210—Drugs and Druggists' Sundries Merchant Wholesalers	7,012	250 employees	6,760	96.4
424690—Other Chemical and Allied Products Merchant Wholesalers	5,487	175 employees	5,197	94.7

[17] Executive Office of the President Office of Management and Budget, North American Industry Classification System, United States, 2022, *https://www.census.gov/naics/reference_files_tools/2022_NAICS_Manual.pdf.* (Accessed 4/2/2024.)

TABLE 2—PERCENT AFFECTED SMALL ENTITIES BY INDUSTRY—Continued

NAICS industry	Firms [18]	SBA size standard [19]	Small firms [20]	Percent small entities (%)
541715—Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).	10,042	1,000 employees	9,599	95.6
611310—Colleges, Universities and Professional Schools	2,494	$34.5 million	1,515	60.8

Based on the American Chemical Society's SciFinder database,[21] DEA identified one entity supplying MDMB-4en-PINACA across the industries 325412, 424210, and 424690. This entity has already registered with DEA to handle controlled substances. Hence, DEA expects none of the entities in the 325412, 424210, and 424690 industries will be affected by this rule. Additionally, DEA expects that the number of researchers working with MDMB-4en-PINACA is small, 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. Also, DEA believes that the researchers working with MDMB-4en-PINACA may also work with other controlled substances; hence, these researchers are likely already registered with DEA and are qualified to handle controlled substances. For these reasons, DEA believes the number of affected researchers that are small entities is not a substantial number of small entities in 541715 and 611310 industries.

In summary, an insubstantial number of small entities will be affected by this proposed rule. As such, the proposed rule, if finalized, is not expected to result in 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. 1501 *et seq.,* DEA has determined and certifies 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 the UMRA of 1995.

Paperwork Reduction Act of 1995

This proposed rule would not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995.[22] Also, this proposed rule would not impose new or modify existing recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. However, this 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. 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.

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 21 CFR 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. Add new paragraph (d)(106); and

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

The addition to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

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

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Signing Authority

This document of the Drug Enforcement Administration was signed on September 30, 2025, by Administrator Terrance 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. 2025–19348 Filed 10–1–25; 8:45 am]

BILLING CODE 4410–09–P

[18] Statistics of U.S. Businesses, 2022 SUSB Annual Data Tables by Establishment Industry, *https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html* (Accessed June 24, 2025).

[19] U.S. Small Business Administration, Table of size standards, Version March 2023, Effective: March 17, 2023, *https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf* (Accessed 6/24/2025) Size standards are based on the number of employees or annual receipts depending on industry.

[20] Based on the estimated number of firms below the SBA size standard for each industry.

[21] SciFinder; Chemical Abstracts Service: Columbus, OH; CAS 2504100–70–1; *https://scifinder.cas.org* (accessed May 14, 2024).

[22] 44 U.S.C. 3501–3521.